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PERFORMANCE TEST REPORT

Cook Sterilization Facility

Ellettsville, Indiana

Submitted To:

Indiana Department of Environmental Management
Office of Air Quality
P.O. Box 6015
100 North Senate Avenue, IGCN 1003
Indianapolis, Indiana 46204

Prepared For:

Cook Incorporated
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ADE Project No. 5450.12

September 10, 2018

[redacted]

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PERFORMANCE TEST CERTIFICATION

1. **Certification of test report and calculations by the team leader of the personnel conducting the sampling procedures and test report author:**

"I certify that the analytical procedures and data presented in this test report are, to the best of my knowledge and belief, true, accurate, and complete."

[redacted]

Zachary T. Thomas
Printed Name of Person Signing

Project Manager
Title

09/10/2018
Date

2. **Certification of calculations and sampling procedures by the person responsible for project QA/QC:**

"I certify that the calculations were performed in accordance with the requirements of the test methods and that the data presented for use in the test report were, to the best of my knowledge and belief, true, accurate, and complete."

[redacted]

Richard J. Tabaczynski
Printed Name of Person Signing

Technical Director
Title

09/10/2018
Date

3. **Certification of test report by the senior staff person at the testing company who is responsible for compiling and checking the test report:**

"I certify that this test report and all attachments were prepared under my direction or supervision in accordance with the project test protocol and that qualified personnel properly gathered and evaluated the test information submitted. Based on my inquiry of the person or persons who performed sampling and analysis relating to the performance test, the information submitted in this test report is, to the best of my knowledge and belief, true, accurate, and complete."

[redacted]

Simon B. Thomas
Printed Name of Person Signing

Principal
Title

09/10/2018
Date

1.0 PERFORMANCE TEST SUMMARY

Cook, Incorporated (Cook) operates a stationary medical device manufacturing and sterilization operation located at 6300 North Mathews Drive in Ellettsville, Indiana. Ethylene Oxide is used at the Cook facility to sterilize medical devices following manufacture before distribution. Cook was granted a Significant Permit Revision to their Federally Enforceable State Operating Permit (FESOP) Renewal No. F 105-27381-00030 on September 7, 2012. The modification was issued to allow Cook to expand the sterilizer operations through the addition of two most recently installed sterilizers designated as S-8 and S-9 to the existing sterilization operations at the facility.

Compliance testing for the sterilization system was conducted on July 27, 2018 after review and acceptance of the testing protocol by Steve Friend of the IDEM Office of Air quality.

Section D.1.5. of the FESOP permit revision imposes performance test requirements on the following control devices:

- The primary wet acid scrubber controlling the sterilizer chamber vent ethylene oxide emissions from the nine sterilization chambers (S-1 through S-9.)

- The primary wet acid pre-scrubber and three dry bed reactors controlling ethylene oxide emissions from the fourteen aeration rooms.

The following Emissions Limitations and Standards are relevant to the Cook Ellettsville Source Test, per Section D.1.1 of the FESOP:

- A single nonregenerable dry bed reactor to reduce ethylene oxide emissions to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, to control the seven (7) sterilization chamber exhaust vents, identified as units S1 through S7.

- A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) with a control efficiency of 99% to control emissions from the fourteen (14) aeration rooms.

1.1 RESULTS SUMMARY

The results of the on-site emissions testing demonstrate that the emissions control equipment is in compliance with the operating permit (FESOP) requirements as follows:

PERFORMANCE TEST RESULTS SUMMARY

Sterilizer Chamber Vent (SCV) Emissions Control Test Runs:

Vent Type	Control Efficiency	Required	Regulatory Status
SCV Run 1 - (4 Sterilizers Simultaneously)	99.98%	99.00%	**In Compliance**
SCV Run 2 - (Sterilizer 8 Only)	99.99%		
SCV Run 3 - (Sterilizer 9 Only)	99.89%		
AVERAGE	**99.95%**		

AERATION ROOM VENT (ARV)

Emissions Control Test Runs

Vent Type	Control Efficiency	Required	Regulatory Status
ARV Header A & B– Run 1	99.885%	99.00%	**In Compliance**
ARV Header A & B– Run 2	99.856%		
ARV Header A & B– Run 3	99.830%		
AVERAGE	**99.86%**		

2.0 BACKGROUND

2.1 STERILIZATION FACILITY

Cook, Incorporated (Cook) operates a stationary medical device manufacturing and sterilization facility located at 6300 North Matthews Drive in Ellettsville, Indiana. Ethylene Oxide (EtO) is used at this facility to sterilize medical devices that are manufactured both on-site and by a local affiliate. The facility is required to comply with 40 CFR Part 63, Subpart O, National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Commercial Ethylene Oxide Sterilization Operations.

Cook was granted a Significant Permit Revision to their Federally Enforceable State Operating Permit (FESOP) Renewal No. F 105-27381-00030 issued on September 7, 2012. The modification was issued to allow Cook to expand the sterilizer operations through the addition of two new sterilizers designated as S-8 and S-9 to the existing sterilization operations at the facility.

The existing facility is permitted to use pure ethylene oxide gas or HCFC gas blends (Oxyfume 2000/2002) as sterilant gasses. HCFC-124 is a hydrofluorocarbon gas that is used as an inert diluent to render the ethylene oxide gas (mixture) nonflammable. Pure ethylene oxide and mixtures of ethylene oxide in air are highly flammable / explosive. The facility currently uses 100% EtO for all sterilization cycles at the Cook Ellettsville Facility.

2.2 STERILIZATION EQUIPMENT

2.2.1 STERILIZATION CHAMBERS (STERILIZERS)

Cook is currently permitted to operate nine (9) sterilization chambers. The sterilizers are designed to operate independently in a batch mode. The sterilizer chamber sizes are shown in the following table:

Table 1
Existing Sterilizers and Specifications

Chamber Number	Internal Volume (ft^3)	Capacity (# of pallets)	Current Status
1	512	3	Operational
2	512	3	Operational
3	512	3	Operational

Chamber Number	Internal Volume (ft^3)	Capacity (# of pallets)	Current Status
4	512	3	Operational
5	175	1	Operational
6	350	2	Operational
7	512	3	Operational
8	1240	8	Operational
9	1240	8	Operational

Each sterilization chamber is evacuated at a nominal flow rate of sixty (60) cubic feet per minute (cfm) by a dedicated, rotary cam nitrogen sealed dry vacuum pump. The vacuum pumps are manifolded to deliver all evacuated gases to the primary wet acid scrubber for treatment prior to discharge to the atmosphere.

Chamber Exhaust Vents (Back Vents) for sterilizers S-1 through S7 are currently routed to a dry bed reactor prior to venting to atmosphere. The Back Vents for sterilizers S-8 and S-9 are uncontrolled and are directly exhausted through dedicated stacks to the atmosphere.

2.2.2 AERATION ROOMS

Cook's sterilization process utilizes a combination of wet acid scrubbing and chemisorption (dry bed reaction) to control ethylene oxide emissions from nine (9) sterilizers and fourteen (14) aeration rooms (hot cells).

- Ethylene oxide emissions from sterilization chamber (vacuum) vents are controlled by a wet acid scrubber with a minimum control (removal) efficiency of 99%.

- Sterilization chamber exhaust vents (back vents) are controlled by a single dry bed reactor with a minimum control efficiency of 99%. The two (2) most recently installed sterilizers, S-8 and S-9, approved for construction in 2012 are not required to have back vent emissions controlled.

- Aeration room (hot cell) vents are controlled by a hybrid technology that consists of a wet acid pre-scrubber and three (3) dry bed reactor units operating in parallel.

Although the wet pre-scrubber in the aeration vent emission control system removes ethylene oxide with an efficiency of ~85%, its principal function is to reduce the mass

loading of ethylene oxide to the chemisorption medium in order to increase bed life and reduce bed replacement costs.

The wet acid scrubbers function by hydrolyzing ethylene oxide. The scrubbing medium is a sulfuric acid solution in which the acid acts as a catalyst. The reaction product is ethylene glycol.

The dry bed reactors (chemisorbers) remove ethylene oxide from gas streams via a gas phase chemical reaction with a granular solid. The solid medium is a proprietary copolymer of styrene and divinylbenzene in the form of small beads. Ethylene oxide gas molecules contact the porous solid and react with active sites distributed throughout the solid matrix. The reaction product is an extended solid with ethylene oxide that is chemically bound to the solid medium.

2.3 STERILIZATION PROCESS

Gas sterilization is a batch process that uses a sealed chamber (sterilizer) in which non-sterile products are exposed to ethylene oxide gas in order to destroy microorganisms and render the products sterile.

Pure ethylene oxide and mixtures of ethylene oxide in air are highly flammable / explosive. HCFC-124 is used as an inert diluent to render the mixture nonflammable. The wet scrubbing or chemisorption processes neither remove HCFC-124, nor affect removal efficiency for ethylene oxide.

Since minor operational changes are continually being made to accommodate the needs of the wide variety of medical products that Cook produces, the procedure described below is typical, and actual sterilization conditions such as contact time and temperatures may vary slightly.

The sterilization procedure currently used by Cook is described as follows:

STEP 1 - Loading

Non-sterile products from post-production packaging operations are palletized and transferred into a sterilization chamber and the door is closed. The products are preconditioned in a moist environment, readying them for sterilization. One (1) to eight (8) pallets of preconditioned products are sterilized at a time.

STEP 2 - Conditioning

The chamber is then partially evacuated and the chamber is conditioned to optimum relative humidity and temperature. This serves to further acclimate the products to the conditions to which they will be exposed during sterilization, thus increasing the effectiveness of the process.

STEP 3 - Sterilization

Following conditioning, the sterilizer is further evacuated and charged with sterilant gas to a maximum charge density of [redacted] of ethylene oxide. These conditions are maintained for an exposure period [redacted] to completely destroy microorganisms that may be present.

STEP 4 - Air Washing

Following the exposure period, the sterilization chamber is flushed ("washed") with air multiple times to remove the sterilant gas. During air washing, the chamber is repeatedly evacuated with a sealed loop vacuum pump and then flooded with air.

STEP 5 - Back venting

Following air washing, the sterilization chamber door is "cracked" open and the back vent blower is operated to exhaust residual ethylene oxide from the chamber. [redacted] Back venting is analogous to the Sterilization Chamber Exhaust Vent cycle identified in EPA's MACT Standard. For Sterilizers S-1 thru S-7, [redacted]

STEP 6 - Product Transfer

During unloading of a sterilizer, the sterilizer door is left open and the back vent blower is operated to help maintain a negative pressure in the sterilization chamber/transfer area. Maintaining a negative pressure by this means helps minimize employee exposure to ethylene oxide residuals and provides greater overall control of ethylene oxide emissions. This exhaust gas is discharged to the emissions control system (dry bed reactor).

Following back venting, the products are manually transferred from the sterilization chamber to the aeration room. One pallet is transferred at a time. [redacted]

STEP 7 - Aeration

The sterilized products are further degassed in the aeration room for a minimum duration of [redacted]. This step allows residual ethylene oxide retained in the sterilized products to diffuse out, rendering the products essentially free of ethylene oxide. Aeration room air is treated by a wet acid (pre)scrubber for the first several hours [redacted] and then a dry bed reactor. For the remainder of the aeration time, aeration room air is discharged directly to the dry bed reactor. 100% of the treated discharge flow from the dry bed reactor is exhausted to the environment to maintain a negative pressure in the aeration room.

2.4 EMISSIONS CONTROL SYSTEM

The emission control system for Cook's sterilization process consists of two (2) wet acid scrubbers and four (4) dry bed reactors. Advanced Air Technologies, Inc. of Corunna, MI manufactured all of the control equipment. The wet-acid scrubbers are model ***Safe Cell II*** and the dry bed reactors model ***DR-490A.***

Each wet-acid scrubber functions by hydrolyzing ethylene oxide into ethylene glycol. The scrubbing medium is a sulfuric acid solution in which the acid acts as a catalyst.

The four (4) dry bed reactors (chemisorbers) remove ethylene oxide from gas streams via a gas phase chemical reaction with a granular solid. The solid medium is a proprietary copolymer of styrene and divinylbenzene in the form of small beads. Ethylene oxide gas molecules contact the porous solid and react with active sites distributed throughout the solid matrix. The small size of the particles increases the surface area to volume ratio of the solid and enhances diffusion of gas through and contact with active sites in the porous matrix. The reaction product is an extended solid with ethylene oxide that is chemically bound to the solid medium.

2.4.1 STERILIZATION CHAMBER VENT (SCV)

One wet-acid scrubber, rated at 360 cfm, treats all sterilization chamber vent emissions. This scrubber is designated as the ***Primary Scrubber*** on the Block Flow Diagram in **Exhibit A.**

2.4.2 AERATION ROOM VENT (ARV)

A second wet-acid scrubber, rated at 1,800 cfm, provides primary control of the aeration room vent (ARV) emissions. This scrubber is designated as the ***Hot Cell Pre-Scrubber*** on the Block Flow Diagram. Exhaust from the Hot Cell Pre-Scrubber passes to three dry bed reactors for final removal of any remaining ethylene oxide in the gas stream. The three reactors are ducted in parallel and have a combined rating of [redacted]. These are designated as the ***Hot Cell Reactors "A", "B"' and "C"***.

Initially, aeration room exhaust gases are directed to the Hot Cell Pre-Scrubber to remove the bulk of the ethylene oxide prior to passing the exhaust through the Hot Cell Reactors. This allows the wet acid scrubber to handle most of the ethylene oxide load and extends the useful life of the adsorbing media in the dry bed reactor.

After progressing to a point in the degassing process where ethylene oxide emissions become substantially lower [redacted] the aeration room vent emissions are diverted to and treated solely by the Hot Cell Reactors.

3.0 REGULATORY BACKGROUND

3.1 OPERATING PERMIT REQUIREMENTS

The facility was constructed and operates in accordance with a Federally Enforceable State Operating Permit (FESOP) issued by the Indiana Department of Environmental Management (No. F105-8436-00030).

In accordance with the FESOP and NESHAP requirements, Cook conducted an initial performance test of the emissions control system on June 4, 1999. The results of this test established that the performance standards specified in the permit and applicable requirements of the NESHAP were being satisfied. As a condition of this operating permit, Cook is required to reduce Chamber Exhaust Vent (CEV) emissions by 99%.

Cook was granted a Significant Permit Revision to their Federally Enforceable State Operating Permit (FESOP) Renewal No. F-105-27381-00030 issued on September 7, 2012. This performance test is intended to satisfy the performance testing requirements associated with the FESOP Significant Permit Revision.

4.0 TESTING OF EMISSIONS CONTROL EQUIPMENT

4.1 EMISSIONS CONTROL OVERVIEW

Cook's emissions control system utilizes a combination of wet-acid scrubbing and chemisorption (dry bed reaction) to control ethylene oxide emissions from nine (9) sterilizers and fourteen (14) aeration rooms (hot cells).

- Ethylene oxide emissions from sterilization chamber (vacuum) vents are controlled by a wet acid scrubber with a minimum control (removal) efficiency of 99%.

- Aeration room (hot cell) vents are controlled by a hybrid technology that consists of a wet acid pre-scrubber and three (3) dry bed reactor units operating in parallel.

- Sterilization chamber exhaust vents (back vents) are controlled by a single dry bed reactor with a minimum control efficiency of 99% for sterilizers S1-S7. Sterilizer back vents (CEVs) for Sterilizers S-8 and S-9 are uncontrolled and are directly exhausted through dedicated stacks to the atmosphere.

4.2 PERFORMANCE TEST

On July 27th of 2018, performance testing was conducted by Atlantic in accordance with the test protocol submitted to IDEM dated June 20, 2018 and the test protocol addendum submitted on July 23, 2018. A copy of the test protocol is included as **Appendix A** of this test report.

The test program was structured to characterize the emissions of the independent emission control systems, multiple sources, and operating sequences at the Ellettsville facility, and successfully demonstrated compliance with all aforementioned standards and conditions.

4.2.1 Compliance Demonstration Test #1: Sterilizer Chamber Vent Standard (SCV) Overview

The current FESOP limits the production of the facility to a maximum of four (4) sterilizers that can be simultaneously discharged. The largest operating sterilizers, S-8 and S-9, along with the two of the remaining originally permitted seven sterilizers (S1 & S4) were charged with Eto for completion of a sterilization cycle under normal operating conditions. The operating sterilizers were concurrently charged with ethylene oxide at a charge density of 500 mg/L for S-1 and S-4, and a charge density of 600 mg/L for

sterilizers S-8 and S-9. The sterilizers were simultaneously evacuated during our scheduled testing (see Section 4.3) time to confirm worst-case emissions control system performance.

This procedure was duplicated in the second and third test runs using the two most recently installed larger chambers individually (S-8 & S-9). Please refer to Section 4.5 for more details regarding the SCV testing methods and procedures.

Average control efficiencies using the three SCV tests represent the emissions control for the facility. The tests successfully demonstrated compliance with the Cook FESOP permit requirements of at least 99% removal efficiency across the control device (see Section 7.0). The FESOP permit has been provided as **Appendix B** and supporting calculations are provided as **Exhibit B** through **Exhibit E** attached**.**

4.2.2 Compliance Demonstration Test #2: Aeration Room Vent Standard (ARV) Overview

An aeration test was run to evaluate the performance efficiency of the wet acid pre-scrubber / dry bed reactor system while production materials are being aerated. Production materials from recent sterilizer loads were aerated following normal operating procedures at the facility.

The ARV test consisted of three back-to-back runs of one-hour duration each. Three one (1) hour runs were completed combining both Header A's and Header B's combined inlet concentration and combined outlet concentration/flow rate. Please refer to Section 4.6 for more details.

Results were reported as the arithmetic average control efficiency for the three runs. This test demonstrated compliance with reference to the Cook FESOP permitwhich requires 99% emission reduction.

4.3 TEST SEQUENCE

In order to facilitate testing of Cook's sterilization and emissions control equipment, the test sequences for the performance test program were established as follows:

Test Sequence Summary (July 27, 2018)	
1. GC Calibration 1 (Method 18):	08:02 am – 08:45 am
2. Sample Point and Sample Line Inspections	09:00 am – 09:35 am
3. Sterilizer Chamber Vent Test # 1 (Simultaneous discharge from four sterilizers: S-1, S-4, S-8 & S-9)	09:57 am – 10:16 am
4. ARV Test Run # 1 (Header A & B): (Ten pallets of sterilized product across two aeration rooms)	11:25 am – 12:20 pm
5. ARV Test Run # 2 (Header A & B): (Ten pallets of sterilized product across two aeration rooms)	12:25 am – 01:20 pm
6. ARV Test Run # 3 (Header A & B): (Ten pallets of sterilized product across two aeration rooms)	01:25 pm – 02:20 pm
7. Sterilizer Chamber Vent Test # 2 (Chamber S-8):	02:36 pm – 02:52 pm
8. Sterilizer Chamber Vent Test # 3 (Chamber S-9):	02:58 pm – 03:14 pm

4.4 PERFORMANCE TEST METHODS

Performance testing of the emission control system was conducted in accordance with applicable portions of 40 CFR **§** 63.363 Compliance and Performance Testing and 63.365 Test Methods and Procedures, supplemented by the methods and procedures described in the Test Protocol dated June 20, 2018 and the addendum to the Test Protocol submitted to IDEM electronically on July 23, 2018 (attached as **Appendix D)**. Testing was structured to demonstrate compliance with two separate emissions control standards in accordance with the provisions of the Significant Permit Revision issued by IDEM on September 7, 2012.

The performance test results were compared with the performance requirements of Cook's operating permit to demonstrate compliance.

4.4.1 EtO CONCENTRATION MEASUREMENTS

EtO mass-mass control efficiency and mass emissions tests were conducted in general accordance with EPA Method 18, § 8.2.2, *Direct Interface Sampling and Analysis Procedure*. A gas chromatograph was used on site to simultaneously monitor the EtO concentration in the source gases upstream and downstream of the emission control device.

Exhaust stack temperature and pressure were monitored in lieu of assuming worst case moisture (3%) or standard temperature, per recommendations by IDEM. Additionally, moisture content was monitored on 1-minute intervals during ARV testing, per recommendations by IDEM.

Sampling ports were located in accordance with EPA Reference Method 1. Sample locations are depicted in the equipment plan and sampling photographs located in **Appendix E.**

4.4.2 VOLUMETRIC FLOW MEASUREMENT

Flow rates were measured in accordance with USEPA Reference Method 2C using a standard pitot tube, inclined-oil manometer and thermocouple.

Exhaust gas composition was assumed to be air and water vapor. The test calculations herein account for atmospheric conditions as the flow measurement results were converted to dscfm. The efficiency calculations for the performance test runs were completed using the calculated 2.68% ambient exhaust moisture contents (monitored over 1-minute intervals) per the addendum to the Performance Test Protocol submitted to Steve Friend at the IDEM Office of Air Quality on June 20, 2018. The addendum has been included as **Appendix D – Section 1.0.** The moisture content was taken into account in the flow calculations, explained further in Section 5.6.

4.5 STERILIZATION CHAMBER VENT (SCV) TESTING

4.5.1 SCV EMISSIONS CONTROL STANDARD

For the Sterilization Chamber Vent (SCV), an emission reduction of at least 99% is specified in the Cook facility's FESOP (105-29042-00030) issued by IDEM.

4.5.2 SCV SAMPLING METHODOLOGY

During the first SCV test run, four (4) operational sterilizers (Chamber No. 1, 4, 8, & 9) were tested empty (without pallets of product) at normal operating conditions at the maximum charge density of [redacted] After a brief stabilization period to simulate the normal sterilization (exposure) cycle, the Sterilization Chamber Vent (SCV) cycle was initiated by simultaneously evacuating all four sterilizers.

The second and third SCV test runs were completed in the same manner for the two most recently installed single sterilizers (S-8 and S-9) as described in Section 4.2.1.

Outlet EtO concentration and flow measurements were taken during the entire Sterilization Chamber Vent phase. EtO mass to the inlet of the Primary Scrubber was calculated by application of the Ideal Gas Law using Equation One in Section 5.1. Outlet concentrations from the Primary Scrubber outlet were analyzed with a SRI Model 8610 portable gas chromatograph (GC) equipped with both a Photo Ionization Detector (PID) and a Flame Ionization Detector (FID).

SCV Test #1 was proposed as the first test run of the compliance test. The four-sterilizer evacuation included Sterilizer 1 (512 Cubic Feet), Sterilizer 4 (512 cubic feet), Sterilizer 8 (1,240 cubic feet) and Sterilizer 9 (1,240 cubic feet). The SCV Test began at 9:57 am and sampling continued on 1-minute intervals for the 18-minute Sterilant Removal Phase. The following was noted during the sampling period:

a. Ambient Moisture (percent)
b. Header Stack flowrate (ft/s)
c. Pressure (inHg)
d. Stack Volume (m^3)
e. Outlet Concentration of EtO
f. Ambient Temperature (Rankine)
g. Scrubber Liquid Level (Pre and Post test)
h. Initial EO charge by sterilizer

During SCV sampling, the following data was recorded:

- Initiation and termination time for each sequence,
- Sterilizer pressure (each sterilizer), at initial charge and at the end of initial post-exposure evacuation,
- Sterilizer temperature (each sterilizer), at initial charge and at the end of initial post-exposure evacuation,
- Scrubber liquid level, and
- EtO charge for each sterilizer.

From this data, the following conditions were established by GC analysis, flow measurements, or engineering calculations:

- Volumetric flow rate at scrubber inlet,
- Concentration of ethylene oxide, in parts per million by volume (ppmv) of primary wet acid scrubber inlet gases,
- Volumetric flow rate of exhaust gases from the primary wet acid scrubber, and
- Concentration of ethylene oxide, in parts per million by volume (ppmv) in exhaust gases from the primary wet acid scrubber.

Cycle Data Reports indicating the Sterilant Removal Phase timelines for sterilizers used during SCV testing are provided in **Appendix H**[1].

4.5.3 SCV SITE-SPECIFIC OPERATING PARAMETER

Under the Cook FESOP permit continuous compliance of the wet-acid scrubber is demonstrated through the ongoing monitoring of a site-specific operating parameter established during compliance testing.

The specified site-specific parameter to be established for the acid-water scrubber was the maximum scrubber liquor tank level during the performance test.

Cook has elected to use the maximum scrubber liquor tank level as the site-specific operating parameter for its SCV Primary Wet Acid Scrubber. The scrubber tank levels recorded during SCV testing are included in the Test Results (**Section 7.0**).

[1] Cook Cycle Data Reports are considered Confidential Business Information

4.6 AERATION ROOM VENT (ARV) TESTING

An aeration room vent test was conducted to evaluate the performance efficiency of the hybrid ethylene oxide control system while production materials are in aeration. Each aeration room has two (2) exhaust ducts.

One exhaust duct connects all aeration cells to a common manifold (Header A) which exhausts to the wet acid pre-scrubber, followed by the dry bed reactor system. The second exhaust duct connects all aeration cells to a separate manifold (Header B) that bypasses the wet acid pre-scrubber and exhausts directly to the (3) dry bed reactor system.

The configuration of the ARV headers is depicted in the Block Flow Diagram attached as **Exhibit A.**

4.6.1 ARV EMISSIONS CONTROL STANDARD

Under § 63.362 of the NESHAP, the emission standard for the Aeration Room Vent is specified as either:

1) An emission reduction of 99%, OR
2) A concentration limit of 1 ppmv, whichever is less stringent.

Cook has elected to control ARV emissions from the outlet of the Hot Cell Reactors by an emission reduction of at least 99%.

4.6.2 ARV SAMPLING METHODOLOGY

The following data was established by on-site sampling / flow measurements:

- Concentration of ethylene oxide, in parts per million by volume (ppmv) in control system inlet gases,
- Concentration of ethylene oxide, in parts per million by volume (ppmv) in dry bed reactor system outlet gases, and,
- Volumetric flow rate of dry bed reactor system outlet duct.
- Moisture content in the combined Header A/Header B Stack

For ARV Test #1, aeration started at 11:25am and the first GC injection was completed at 11:28am. ARV Test #2 was initiated at 12:25pm and ARV Test #3 was initiated at 1:25pm.

The following conditions were noted within the aeration headers every 60 seconds throughout each 55-minute testing period (See **Exhibit E** attached):

a. ΔP (inHg)
b. √ΔP
c. Temperature (ºF)

Additionally, the following was collected on five-minute intervals throughout each 55-minute testing period:

a. Inlet and Outlet EtO concentrations

4.6.3 ARV HEADER A & HEADER B COMBINED EMISSIONS

Aeration testing was completed with two of the operating aeration rooms (aeration cells) fully loaded with 10 pallets of freshly sterilized product. All exhaust gases from the two aeration cells were evacuated using Header A & Header B.

For a one-hour testing period, EtO concentrations at the inlet and outlet of the ARV emissions control system were simultaneously measured with a SRI, Model 8610, portable gas chromatograph (GC), equipped with dual, heated sample loops and injectors, dual columns, and dual detectors. A flame ionization detector (FID) was used to quantify emissions at the emission control device inlet where Header A & B converged, and a photo ionization detector (PID) was used to quantify emissions at the emission control device outlet.

After completing ARV Test Run # 1, the procedure was repeated two additional times. Control system efficiencies were determined using Equation 5 in Section 5.5. Test results are reported as the arithmetic average control efficiency calculated for the three (3) test runs.

5.0 CONTROL-EFFICIENCY / MASS-EMISSIONS CALCULATIONS

5.1 CALCULATION OF MASS BY IDEAL GAS LAW

The inlet mass of EtO from the sterilization chamber to emissions control during Sterilizer Chamber Venting was determined by using the following equation:

$$W_C = \frac{MW_{EtO} * N_{EtO} * P * V}{R * T} \quad \textbf{(Equation 1)}$$

Where:

Variable:	Description:	Unit:
W_C	Mass of Ethylene Oxide charged	lb_m
MW_{EtO}	Molecular weight of Ethylene Oxide	lb/mol
N_{EtO}	Mole fraction of Ethylene Oxide = MW_{EtO} / $M_{\%EtO}$	
$M_{\%EtO}$	Weight percent of EtO in the sterilant gas	44.05 / $W_{\%Eto}$
P	Chamber pressure	psia
V	Chamber volume	ft^3
R	Gas constant	$\frac{(psia) \cdot (ft^3)}{(mol) \cdot (^oR)}$
T	Temperature	^oR

5.2 RESIDUAL MASS CHARGE

The residual mass of ethylene oxide in the sterilizer (W_R) were determined by recording the chamber temperature, pressure, and volume after the completion of the first evacuation and using the following equation:

$$W_R = \frac{MW_{EtO} * N_{EtO} * P * V}{R * T} \quad \textbf{(Equation 2)}$$

Note: Standard conditions are 68°F and 1 atm

5.3 INLET MASS TO CONTROL SYSTEM

The total mass of ethylene oxide to the inlet to the control device (W_i) were calculated by subtracting the residual mass (W_R) calculated with Equation 2 from the charged weight (W_C) calculated by Equation 1.

$$\dot{W}_i = W_C - W_R \quad \textbf{(Equation 3)}$$

5.4 OUTLET MASS FROM CONTROL SYSTEM

During the sterilizer exhaust cycle, the mass of ethylene oxide emitted from the control device outlet (W_{out}) was calculated by measuring the flow rate through the control device exhaust continuously during the first evacuation using procedures found in 40 CFR part 60. Flow rates were recorded at approximately one-minute intervals throughout the test cycle, taking the first reading within fifteen (15) seconds after time zero, defined at the moment when the pressure in the sterilizer is released.

The concentration of ethylene oxide was determined by the application of Test Method 18 using an on-site gas chromatograph. The outlet mass flow rate (M_{out}) from the control system was calculated using the following equation:

$$\dot{W}_{out} = \frac{\dot{V} * t_C * MW_{EtO} * (\frac{1}{10^6} \cdot [EtO])}{V_{mol}} \qquad \textbf{(Equation 4)}$$

Where:

Variable:	Description:	Unit:
$\dot{V}$	Corrected volumetric flow rate @ STP	ft^3/min
t_C	Total Cycle Time	min
MW_{EtO}	Molecular weight of Ethylene Oxide	44.05 lb EtO/lbmol
[EtO]	EtO concentration	ppm
$\frac{1}{10^6}$	Conversion factor, ppmv per "*cubic foot per cubic foot*"	
V_{mol}	Volume per pound mole @ STP	385.32 ft^3/lbmol

Equation 4 was used to calculate the inlet and outlet mass numbers for both the Primary and Secondary Aeration Room Vent Control efficiency calculations.

5.5 CONTROL DEVICE EFFICIENCY

The efficiency (η) of the control device was calculated with the following equation:

$$\eta = \frac{\dot{W}_i - \dot{W}_{out}}{\dot{W}_i} \times 100 \quad \textbf{(Equation 5)}$$

Where:

η	=	*Efficiency (%)*
$\dot{W}_i$	=	*Mass flow rate into the control device*
$\dot{W}_{out}$	=	*Mass flow rate out of the control device*

Calculations for the above equations are attached as Exhibits to this report.

5.6 VOLUMETRIC FLOW CALCULATIONS

Calculations herein account for atmospheric conditions. The efficiency calculations for the performance test runs were completed using the average stack moisture content of 2.68% per the addendum to the Performance Test Protocol submitted to the IDEM office of Air Quality on June 20, 2018. The Addendum has been provided as **Appendix D.**

Stack volumetric flowrates ($\dot{V}$) were calculated using the following equation:

$$\dot{V} = \frac{N_{MC} * v * A * T * P}{T_1 * P_1} \quad \textbf{(Equation 6)}$$

Where:

Variable:	Description:	Unit:
$\dot{V}$	Volumetric Flowrate	dscfm
N_{MC}	Moisture Content	2.68%
v	velocity	ft/sec
A	Stack Area	[redacted]
T	Standard Temperature	°R
P	Standard Pressure	inHg
T_1	Stack Temperature	°R
P_1	Stack Pressure	inHg

5.6.1 FLOW DATA AND CALCULATIONS

The flow of EtO in the stack was calculated using the equation above. The calculation for the flow of EtO, resulting in Dry Standard CFM, uses the stack moisture content of 2.68%.

5.6.1.1 SCV TESTS - FLOW CALCULATION

SCV testing was completed according to procedures outlined in **Section 4.5.2** of this report. SCV Test #1 included the simultaneous evacuation of sterilizers S-1, S-4, S-8 and S-9. SCV Test #2 was completed using Sterilizer S-8 only and SCV Test #3 was completed using Sterilizer S-9 only.

The testing conditions noted during the source testing are shown in the following table:

Test	Moisture Content (%)	Velocity (ft/sec)	Stack Area (m^3)	Pressure (inHg)	Temp. (^oR)
SCV Test #1	2.68%	[redacted]	[redacted]	29.20	546
SCV Test #2	2.68%	[redacted]	[redacted]	27.90	547
SCV Test #3	2.68%	[redacted]	[redacted]	29.20	547

The calculated flow rates for the stack during SCV Testing were as follows (see **Exhibit E**):

- SCV Test #1 - 73.8 Dry Standard CFM (dscfm)
- SCV Test #2 - 73.7 dscfm
- SCV Test #3 - 73.7 dscfm.

The above values were measured on-site during testing according to the procedures outlined in **Section 4.0** to calculate Mass Flow of EtO for each corresponding test. The mass flow the period of time (test period) was used to determine the total mass emissions. **Equation 4** from **Section 5.4** combines these two calculations.

A copy of these calculation sheets and velocity traverse data is included with the SCV Test Data in **Appendix A.**

6.0 QUALITY ASSURANCE / QUALITY CONTROL

6.1 FIELD TESTING QUALITY ASSURANCE

Before the start of analytical work, a system blank was analyzed to insure that the sampling system was free of EtO. Air was drawn through the sampling system lines to the GC for analysis. After determining that the sampling system was clean, a sample of source gas was injected into the sampling system and analyzed to determine the concentration of any residual EtO present in the sample.

6.2 TEST REPORT QUALITY ASSURANCE

Before submittal, this test report underwent a tiered review by Atlantic staff. A signed certification attesting to the review is presented at the beginning of the report.

1. An initial review of the report and calculations was performed by the report author / project manager.
2. A second review was performed by a colleague (staff engineer / scientist).
3. A final review was performed by the principal of Atlantic's Division of Air Quality.

6.3 CALIBRATION PROCEDURES

The calibration of all applicable manual sampling equipment generally followed the QA / QC procedures in 40 CFR 60, the EPA *Quality Assurance Handbook, Volume III, APTA0576*, and all applicable equipment manufacturers' procedures. Any variations from standard EPA test methods and sampling procedures have been noted.

EtO concentrations at the inlet and outlet of the emissions control device were simultaneously measured following the procedures delineated in CARB Method 431. Vented gas was analyzed by an SRI, Model 8610C, portable gas chromatograph (GC), equipped with dual, heated sample loops and injectors, dual columns, and dual detectors. A flame ionization detector (FID) was used to quantify emissions at the emission control device inlet, and a photo ionization detector (PID) was used to quantify emissions at the emission control device outlet.

The GC system was calibrated at the beginning and conclusion of the performance test. Each of the calibration standards was taken from a separate, certified manufacturer's cylinder. Each of the three calibration run results were within 5% of each other satisfying requirements set forth in EPA's Method 18, § 8.2.2, *Direct Interface Sampling and Analysis Procedure*.

All calibration gases and support gases were of the highest purity and quality available. A copy of the calibration data is provided in **Appendix F** and velocity/traverse logs are provided in **Appendix A** of this report.

7.0 PERFORMANCE TEST RESULTS

The following control efficiencies of the EtO emission control systems for the Sterilizer Chamber Vent (SCV) and Aeration Room Vents (ARV) were calculated using Equation 5 in Section 5.5.

7.1 SCV EMISSIONS CONTROL TEST RUNS:

Vent Type	Control Efficiency	Required	Regulatory Status
SCV Run 1 - (4 Sterilizers Simultaneously)	99.98%	99.00%	**In Compliance**
SCV Run 2 - (Sterilizer 8 Only)	99.99%		
SCV Run 3 - (Sterilizer 9 Only)	99.89%		
AVERAGE	**99.95%**		

Average control efficiency was calculated based on the arithmetic mean of the three test runs. **The average tested control efficiency for the EtO emissions control system from the sterilization chamber vents is 99.95%.**

7.2 ARV EMISSIONS CONTROL TEST RUNS

Vent Type	Control Efficiency	Required	Regulatory Status
ARV Header A & B– Run 1	99.89%	99.00% (or 1ppm)	**In Compliance**
ARV Header A & B– Run 2	99.86%		
ARV Header A & B– Run 3	99.83%		
AVERAGE	**99.86%**		

Average control efficiency was calculated based on the arithmetic mean of the three test runs. **The average tested control efficiency for the EtO emissions control reduction system from the aeration room vents was 99.86%.**

7.3 SCV PRIMARY WET-ACID SCRUBBER - LIQUOR LEVELS:

The wet acid liquor levels for the holding tank were measured before and after the performance testing on July 27, 2018. The levels of the acid within the tanks were recorded and shown below. Pictures of the tanks have also been included in **Appendix E.**

Tank:	Prior to Tests	After Tests
Common Tank	73 1/4"	73 1/4"
Scrubber Tank	100 1/2"	100 1/2"
Aeration Tank	103"	103"

The measurements taken prior to the tests were recorded at 9:06 am. The measurements taken after the tests were recorded at 3:46 pm.

EXHIBIT A

[redacted]

[redacted]

EXHIBIT B

SCV TEST #1 SUMMARY

Confidential Business Information

ECSi, Inc.

Ethylene Oxide Mass Emissions Data and Calculations

Exhaust Run #1 (Scrubber Outlet) - Chambers 1, 4, 8 & 9
Cook Medical, Inc. - Ellettsville, IN
July 27, 2018

DeltaP	SqRtDeltaP	Temp (F)	ppm EtO
0.010	0.1000	86	0.01
0.010	0.1000	86	0.01
0.010	0.1000	86	55.5
0.010	0.1000	86	126
0.010	0.1000	86	139
0.010	0.1000	86	146
0.010	0.1000	86	145
0.010	0.1000	86	137
0.010	0.1000	86	124
0.010	0.1000	86	130
0.010	0.1000	86	127
0.010	0.1000	86	126
0.010	0.1000	86	122
0.010	0.1000	86	129
0.010	0.1000	87	115
0.010	0.1000	87	47.2
0.010	0.1000	86.1	**104.3**
	=	546	degR

mw =	28.51	
stack area =	[redacted]	
press =		
Tstd =	528	
Pstd =	29.92	
Cp =	0.99	
Kp =	85.49	
Velocity =	[redacted]	ft/sec
Flow =		**dscfm**
MWeto =	44.05	
MolVol =	385.32	
ppmv/ft3 =	1000000	
EtO Mass Flow =	**0.0008797**	**lbs/min**
min/cycle =	19	
EtO Emissions =	**0.016714**	**lbs/cycle**
Start Time:	957	
Stop Time:	1016	

INLET CALCULATION:

Chamber 1

Pre-Evac:				Post-Evac:			
	V =	[redacted]	ft3		V =	[redacted]	ft3
	P =		in Hg Abs		P =		in Hg Abs
	T =		degF		T =		degF
	R =	10.73			R =	10.73	
	mw =	44.05			mw =	44.05	
	lbs EtO @ 100% =	49.66	lbs		lbs EtO @ 100% =	16.04	lbs

Initial EtO = Scale Wt. =	16.7	lbs
% EtO @ Chamber = Scale Wt. / lbs EtO @ 100% (Pre) =	33.6	%
Final EtO = % EtO @ Chamber X lbs EtO @ 100% (Post) =	5.40	lbs
Chamber 3 Inlet EtO = Initial EtO - Final EtO =	**11.3**	**lbs**

Chamber 4

Pre-Evac:				Post-Evac:			
	V =	[redacted]	ft3		V =	[redacted]	ft3
	P =		in Hg Abs		P =		in Hg Abs
	T =		degF		T =		degF
	R =	10.73			R =	10.73	
	mw =	44.05			mw =	44.05	
	lbs EtO @ 100% =	49.56	lbs		lbs EtO @ 100% =	16.07	lbs

Initial EtO = Scale Wt. =	16.6	lbs
% EtO @ Chamber = Scale Wt. / lbs EtO @ 100% (Pre) =	33.5	%
Final EtO = % EtO @ Chamber X lbs EtO @ 100% (Post) =	5.38	lbs
Chamber 6 Inlet EtO = Initial EtO - Final EtO =	**11.2**	**lbs**

Chamber 8

Pre-Evac:	V =	[redacted]	ft3	Post-Evac:	V =	[redacted]	ft3
	P =	[redacted]	in Hg Abs		P =	[redacted]	in Hg Abs
	T =	[redacted]	degF		T =	[redacted]	degF
	R =	10.73			R =	10.73	
	mw =	44.05			mw =	44.05	
	lbs EtO @ 100% =	119.51	lbs		lbs EtO @ 100% =	38.89	lbs

Initial EtO = Scale Wt. =	41.0	lbs
% EtO @ Chamber = Scale Wt. / lbs EtO @ 100% (Pre) =	34.3	%
Final EtO = % EtO @ Chamber X lbs EtO @ 100% (Post) =	13.34	lbs
Chamber 8 Inlet EtO = Initial EtO - Final EtO =	**27.7**	**lbs**

Chamber 9

Pre-Evac:	V =	[redacted]	ft3	Post-Evac:	V =	[redacted]	ft3
	P =	[redacted]	in Hg Abs		P =	[redacted]	in Hg Abs
	T =	[redacted]	degF		T =	[redacted]	degF
	R =	10.73			R =	10.73	
	mw =	44.05			mw =	44.05	
	lbs EtO @ 100% =	119.51	lbs		lbs EtO @ 100% =	38.76	lbs

Initial EtO = Scale Wt. =	40.4	lbs
% EtO @ Chamber = Scale Wt. / lbs EtO @ 100% (Pre) =	33.8	%
Final EtO = % EtO @ Chamber X lbs EtO @ 100% (Post) =	13.10	lbs
Chamber 9 Inlet EtO = Initial EtO - Final EtO =	**27.3**	**lbs**
TOTAL INLET ETO =	**77.5**	**lbs**
CONTROL EFFICIENCY =	**99.97843**	**%**

EXHIBIT C

SCV TEST #2 SUMMARY

Confidential Business Information

ECSi, Inc.

Ethylene Oxide Mass Emissions Data and Calculations

Run #2 (Scrubber Outlet) - Chamber #8
Cook Medical, Inc. - Ellettsville, IN
July 27, 2018

DeltaP	SqRtDeltaP	Temp (F)	ppm EtO
0.01	0.1000	86	0.01
0.01	0.1000	86	0.01
0.01	0.1000	86	0.01
0.01	0.1000	87	0.01
0.01	0.1000	87	0.01
0.01	0.1000	87	0.01
0.01	0.1000	87	0.01
0.01	0.1000	87	0.01
0.01	0.1000	87	0.01
0.01	0.1000	87	0.01
0.01	0.1000	86	0.01
Average =			
0.0100	0.1000	86.6	**0.0100**
	=	547	degR

mw =	28.51	
stack area =	[redacted]	
press =		
Tstd =	528	
Pstd =	29.92	
Cp =	0.99	
Kp =	85.49	
Velocity =	[redacted]	ft/sec
Flow =	[redacted]	**dscfm**
MWeto =	44.05	
MolVol =	385.32	
ppmv/ft3 =	1000000	
EtO Mass Flow =	**0.00000008**	**lbs/min**
evac start =	1436	
evac stop =	1452	
min/cycle =	16	
EtO Emissions =	**0.00000135**	**lbs/cycle**

INLET CALCULATION:

Pre-Evac:				Post-Evac:			
	V =	[redacted]	ft3		V =	[redacted]	ft3
	P =	[redacted]	in Hg Abs		P =	[redacted]	in Hg Abs
	T =	[redacted]	degF		T =	[redacted]	degF
	R =	10.73			R =	10.73	
	mw =	44.05			mw =	44.05	
	lbs EtO @ 100% =	119.73	lbs		lbs EtO @ 100% =	38.76	lbs

Initial EtO = Scale Wt. =	40.9	lbs
% EtO @ Chamber = Scale Wt. / lbs EtO @ 100% (Pre) =	34.2	%
Final EtO = % EtO @ Chamber X lbs EtO @ 100% (Post) =	13.2	lbs
INLET ETO = Initial EtO - Final EtO =	**27.7**	**lbs**
CONTROL EFFICIENCY =	**99.999995**	**%**

EXHIBIT D

SCV TEST #3 SUMMARY

Confidential Business Information

ECSi, Inc.

Ethylene Oxide Mass Emissions Data and Calculations

Run #3 (Scrubber Outlet) - Chamber #9
Cook Medical, Inc. - Ellettsville, IN
July 27, 2018

DeltaP	SqRtDeltaP	Temp (F)	ppm EtO
0.01	0.1000	87	246
0.01	0.1000	87	367
0.01	0.1000	87	303
0.01	0.1000	87	232
0.01	0.1000	87	184
0.01	0.1000	87	146
0.01	0.1000	87	154
0.01	0.1000	87	9.63
0.01	0.1000	87	0.01
0.01	0.1000	87	425
0.01	0.1000	86	369
Average =			
0.0100	0.1000	86.9	**221.4**
	=	547	degR

mw =	28.51	
stack area =	[redacted]	
press =		
Tstd =	528	
Pstd =	29.92	
Cp =	0.99	
Kp =	85.49	
Velocity =	[redacted]	ft/sec
Flow =	[redacted]	**dscfm**
MWeto =	44.05	
MolVol =	385.32	
ppmv/ft3 =	1000000	
EtO Mass Flow =	**0.00186630**	**lbs/min**
evac start =	1458	
evac stop =	1514	
min/cycle =	16	
EtO Emissions =	**0.02986083**	**lbs/cycle**

INLET CALCULATION:

Pre-Evac:	V =	[redacted]	ft3	Post-Evac:	V =	[redacted]	ft3
	P =	[redacted]	in Hg Abs		P =	[redacted]	in Hg Abs
	T =	[redacted]	degF		T =	[redacted]	degF
	R =	10.73			R =	10.73	
	mw =	44.05			mw =	44.05	
	lbs EtO @ 100% =	119.73	lbs		lbs EtO @ 100% =	38.76	lbs

Initial EtO = Scale Wt. =	40.8	lbs
% EtO @ Chamber = Scale Wt. / lbs EtO @ 100% (Pre) =	34.1	%
Final EtO = % EtO @ Chamber X lbs EtO @ 100% (Post) =	13.2	lbs
INLET ETO = Initial EtO - Final EtO =	**27.6**	**lbs**
CONTROL EFFICIENCY =	**99.8918**	**%**

EXHIBIT E

ARV TESTS 1-3 SUMMARY

Confidential Business Information

ECSi, Inc.

Ethylene Oxide Mass Emissions Data and Calculations

Cook Medical, Inc. - Ellettsville, IN
7-27-18 - Aeration Runs 1-3 - Header A/B

DeltaP	SqRtDeltaP	Temp (F)	ppm EtO
Run #1			
0.060	0.2449	96	0.01
0.060	0.2449	96	0.01
0.060	0.2449	96	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	96	0.01
0.060	0.2449	96	0.01
0.060	0.2449	96	0.01
0.060	0.2449	96	0.01
0.060	0.2449	96	0.01
0.060	0.2449	96	0.01
0.060	0.2449	97	0.01
Run #2		Average =	0.0100
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	98	0.01
0.060	0.2449	98	0.01
0.060	0.2449	98	0.01
0.060	0.2449	98	0.01
0.060	0.2449	98	0.01
0.060	0.2449	98	0.01
Run #3		Average =	0.0100
0.060	0.2449	98	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
0.060	0.2449	97	0.01
		Average =	0.0100
3 Run Average =			
0.060	0.2449	96.9	**0.0100**
		= 557	degR

mw =	28.51	
stack area =	[redacted]	
press =	[redacted]	
Tstd =	528	
Pstd =	29.92	
Cp =	0.99	
Kp =	85.49	
Velocity =	[redacted]	ft/sec
Outlet Flow =	[redacted]	**dscfm**
MWeto =	44.05	
MolVol =	385.32	
ppmv/ft3 =	1000000	

Run #1 Outlet

EtO Mass Flow =	**0.000002**	**lbs/min**
EtO Mass Flow =	**0.000127**	**lbs/hr**

Run #2 Outlet

EtO Mass Flow =	**0.000002**	**lbs/min**
EtO Mass Flow =	**0.000127**	**lbs/hr**

Run #3 Outlet

EtO Mass Flow =	**0.000002**	**lbs/min**
EtO Mass Flow =	**0.000127**	**lbs/hr**

TABLE 1
ETHYLENE OXIDE CONTROL EFFICIENCY - AERATION - HEADER A/B
OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE
OPERATED BY COOK MEDICAL, INC.
IN ELLETTSVILLE, INDIANA
ON JULY 27, 2018

RUN NUMBER	INJECTION TIME	INLET ETO CONC. (PPM)(1)	OUTLET ETO CONC. (PPM)(2)	ETO CONTROL EFFICIENCY	
1(3)	1128	15.6	0.01	99.9359	
1	1133	11.6	0.01	99.9138	
1	1138	8.60	0.01	99.8837	
1	1143	7.12	0.01	99.8596	
1	1148	8.00	0.01	99.8750	
1	1153	9.37	0.01	99.8933	
1	1158	9.50	0.01	99.8947	
1	1203	8.94	0.01	99.8881	
1	1208	9.02	0.01	99.8891	
1	1213	7.22	0.01	99.8615	
1	1218	8.69	0.01	99.8849	**Run 1 avg**
1	1223	6.50	0.01	99.8462	99.885
2(4)	1228	7.41	0.01	99.8650	
2	1233	6.81	0.01	99.8532	
2	1238	7.38	0.01	99.8645	
2	1243	7.47	0.01	99.8661	
2	1248	7.33	0.01	99.8636	
2	1253	5.46	0.01	99.8168	
2	1258	5.79	0.01	99.8273	
2	1303	7.48	0.01	99.8663	
2	1308	7.17	0.01	99.8605	
2	1313	6.07	0.01	99.8353	
2	1318	7.24	0.01	99.8619	
2	1323	8.99	0.01	99.8888	**Run 2 avg**
3(5)	1328	6.95	0.01	99.8561	99.856
3	1333	5.75	0.01	99.8261	
3	1338	6.11	0.01	99.8363	
3	1343	6.51	0.01	99.8464	
3	1348	6.42	0.01	99.8442	
3	1353	4.68	0.01	99.7863	
3	1358	5.28	0.01	99.8106	
3	1403	5.36	0.01	99.8134	
3	1408	6.35	0.01	99.8425	
3	1413	4.87	0.01	99.7947	
3	1418	6.38	0.01	99.8433	**Run 3 avg**
3	1423	7.38	0.01	99.8645	99.830
TIME-WEIGHTED AVERAGE:		**7.411**	**0.0100**	**99.8572**	
		MCDEP REQUIRED CONTROL EFFICIENCY:		**99%**	

Notes:
(1) - PPM = parts per million by volume
(2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
(3) - Test Run #1 started at 11:25, ended at 12:25.
(3) - Test Run #2 started at 12:25, ended at 13:25.
(3) - Test Run #3 started at 13:25, ended at 14:25.

ECSi

APPENDIX A

TESTING LOG SHEETS, VELOCITY & TRAVERSE DATA

Confidential Business Information

ECSI, INC. - VELOCITY TRAVERSE DATA

Client: Cook Medical, Inc. Run #: 1 Date: 3/14/2013 Port Sketch:

Location: Ellettsville, Indiana Probe Type: Std Baro Press: 29.55

Source: Dry Bed Scrubber Inlet Stack I.D.: [redacted] DSCFM: [redacted]

	Port 1							Port 2						
Inches From Port	Point#	Delta P Low	Delta P High	Delta P Average	Delta P Sq Root	Stack Temp (F)	Cyclonic Angle	Point#	Delta P Low	Delta P High	Delta P Average	Delta P Sq Root	Stack Temp (F)	Cyclonic Angle
0.5	1	0.05	0.06	0.055	0.2345	87	0	1	0.05	0.06	0.055	0.2345	87	0
1.6	2	0.06	0.06	0.06	0.2449	87	0	2	0.06	0.06	0.06	0.2449	87	0
2.8	3	0.06	0.06	0.06	0.2449	87	0	3	0.06	0.06	0.06	0.2449	87	0
4.2	4	0.06	0.07	0.065	0.2550	87	0	4	0.06	0.07	0.065	0.2550	87	0
6.0	5	0.06	0.07	0.065	0.2550	87	0	5	0.06	0.07	0.065	0.2550	87	0
8.6	6	0.06	0.07	0.065	0.2550	87	0	6	0.06	0.07	0.065	0.2550	87	0
15.4	7	0.07	0.08	0.075	0.2739	87	0	7	0.07	0.08	0.075	0.2739	87	0
18.0	8	0.07	0.08	0.075	0.2739	87	0	8	0.07	0.08	0.075	0.2739	87	0
19.8	9	0.07	0.07	0.07	0.2646	87	0	9	0.06	0.07	0.065	0.2550	87	0
21.2	10	0.06	0.06	0.06	0.2449	88	0	10	0.06	0.07	0.065	0.2550	87	0
22.4	11	0.06	0.06	0.06	0.2449	88	0	11	0.06	0.06	0.06	0.2449	87	0
23.5	12	0.05	0.06	0.055	0.2345	88	0	12	0.05	0.06	0.055	0.2345	88	0
	13							13						
	14							14						
	15							15						
	16							16						
	17							17						
	18							18						
	19							19						
	20							20						
	21							21						
	22							22						
	23							23						
	24							24						
									Average Values:		0.0638	0.2522	87.2	0.0

ECSi - VELOCITY TRAVERSE DATA

Client: Cook Medical, Inc. Run #: 1 Date: 3/14/2013 Port Sketch:

Location: Ellettsville, Indiana Probe Type: Std Baro Press: 29.55

Source: Packed Tower Scrubber Outlet Stack I.D.: [redacted] DSCFM: [redacted]

	Port 1							Port 2						
Inches From Port	Point#	Delta P Low	Delta P High	Delta P Average	Delta P Sq Root	Stack Temp (F)	Cyclonic Angle	Point#	Delta P Low	Delta P High	Delta P Average	Delta P Sq Root	Stack Temp (F)	Cyclonic Angle
0.2	1	0.005	0.005	0.005	0.0707	63	0	1	0.005	0.005	0.005	0.0707	63	0
0.6	2	0.01	0.01	0.01	0.1000	64	0	2	0.01	0.01	0.01	0.1000	63	0
1.2	3	0.01	0.01	0.01	0.1000	64	0	3	0.01	0.01	0.01	0.1000	64	0
2.0	4	0.015	0.015	0.015	0.1225	64	0	4	0.015	0.015	0.015	0.1225	64	0
4.0	5	0.015	0.015	0.015	0.1225	64	0	5	0.015	0.015	0.015	0.1225	64	0
4.9	6	0.01	0.01	0.01	0.1000	64	0	6	0.01	0.01	0.01	0.1000	64	0
5.4	7	0.01	0.01	0.01	0.1000	64	0	7	0.01	0.01	0.01	0.1000	64	0
5.8	8	0.005	0.005	0.005	0.0707	64	0	8	0.005	0.005	0.005	0.0707	64	0
	9							9						
	10							10						
	11							11						
	12							12						
	13							13						
	14							14						
	15							15						
	16							16						
	17							17						
	18							18						
	19							19						
	20							20						
	21							21						
	22							22						
	23							23						
	24							24						
									Average Values:		0.0100	0.0983	63.8	0.0

ARV Run #1-3 (11:25am-2:20pm)

Stack Moisture Calculations

		Wet Bulb (degF)		Dry Bulb(degF)		RH % Average
		[redacted]		[redacted]		[redacted]
lbs H2O/lb dry air (per chart)	=	[redacted]				
Volume Fraction @ dry air	=	lbs H2O / lb dry air	X	[redacted] / mole air	X	1 mole H2O / 18 lbs H2O
	=	[redacted]	X	[redacted]	X	[redacted]
	=	[redacted]				
Volume Fraction @ wet air	=	Volume Fraction (dry) / 1 - Volume Fration (dry)				
Moisture	=	[redacted] %				

[redacted]

Start 11:25 AM

Stack Monitoring - ARV

Run #	ARV #1

Sample Number	Time	% Relative Humidity			% Moisture
		Supply Bulb 1	Return Bulb 2	Average	
1	11:25	41.2	41.7		
2	11:26	41.4	41.7		
3	11:27	41.3	41.6		
4	11:29	41.1	41.7		
5	11:31	40.8	41.4		
6	11:32	40.3	40.9		
7	11:33	40.9	41.2		
8	11:34	40.8	42.1		
9	11:35	41.0	41.1		
10	11:37	41.3	41.5		
11	11:38	40.7	41.6		
12	11:39	41.2	41.6		
13	11:40	40.9	41.3		
14	11:41	40.5	40.9		
15	11:42	40.6	41.1		
16	11:44	40.3	40.5		
17	11:45	40.7	41.3		
18	11:46	40.5	41.1		
19	11:47	40.4	41.5		
20	11:48	41.1	41.4		
21	11:49	40.7	41.3		
22	11:50	40.7	41.1		
23	11:51	40.6	40.6		
24	11:52	40.4	40.7		
25	11:53	40.2	41.3		
26	11:54	40.9	41.4		
27	11:55	40.2	40.8		
28	11:57	40.9	41.0		
29	11:58	40.5	41.1		
30	11:59	40.6	41.4		
31	12:00	40.1	40.6		
32	12:01	40.6	41.2		
33	12:02	40.7	41.1		
34	12:03	40.4	40.6		
35	12:04	40.2	40.6		
36	12:05	40.4	41.0		
37	12:06	40.0	41.0		
38	12:07	40.3	40.5		

39	12:08	40.4	41.1		
40	12:09	40.2	41.4		
41	12:10	40.7	40.4		
42	12:11	40.8	40.9		
43	12:12	40.1	39.9		
44	12:13	40.1	40.5		
45	12:14	40.8	40.4		
46	12:15	40.5	41.0		
47	12:16	40.2	40.9		
48	12:17	39.8	40.9		
49	12:18	39.5	39.7		
50	12:19	39.1	39.3		
51	12:21	38.9	39.9		
52	12:23	38.5	38.7		
53	12:24	38.5	38.7		
54	12:25	37.5	38.1		
55					
56					
57					
58					
59					
60					

Start 1:25 PM

Stack Monitoring - ARV

Run #	3

Sample Number	Time	% Relative Humidity			% Moisture
		Bulb 1	Bulb 2	Average	
1	~~1:25~~	~~39.0~~ ZT	~~39.7~~ ZT		
2	1:26	39.1	39.7		
3	1:27	38.8	38.5		
4	1:28	38.5	38.7		
5	1:29	38.8	39.5		
6	1:30	39.1	39.4		
7	1:31	38.9	39.0		
8	1:32	38.7	39.0		
9	1:33	39.5	39.7		
10	1:34	39.0	39.5		
11	1:35	39.1	38.5		
12	1:36	39.3	39.4		
13	1:37	39.4	38.5		
14	1:38	39.1	39.0		
15	1:39	~~38~~.7	38.9		
16	1:40	38.9	38.5		
17	1:41	38.9	39.1		
18	1:42	38.6	39.0		
19	1:44	38.7	39.1		
20	1:45	39.0	39.0		
21	1:46	39.1	39.5		
22	1:47	39.0	39.5		
23	1:48	39.0	39.0		
24	1:49	39.4	39.7		
25	1:50	39.5	39.6		
26	1:52	38.7	39.9		
27	1:53	39.7	39.7		
28	1:54	39.0	39.4		
29	1:55	39.1	39.3		
30	1:56	38.9	39.1		
31	1:57	38.6	38.9		
32	1:58	38.7	38.8		
33	1:59	39.9	38.5		
34	2:00	38.1	38.7		
35	2:01	38.5	38.9		
36	2:03	38.0	38.5		
37	2:04	38.3	38.4		
38	2:05	38.7	38.9		

39	2:06	39.1	39.5		
40	2:07	39.2	39.6		
41	2:08	39.5	39.6		
42	2:10	39.6	39.8		
43	2:11	39.5	39.7		
44	2:12	39.6	39.8		
45	2:13	39.4	39.3		
46	2:14	39.5	39.7		
47	2:16	39.3	39.6		
48	2:18	39.1	39.4		
49	2:20	39.3	39.4		
50	2:22	39.1	39.5		
51	2:25	39.0	39.2		
52					
53					
54					
55					
56					
57					
58					
59					
60					

Start 12:25

Stack Monitoring - ARV

Run #	2

Sample Number	Time	% Relative Humidity			% Moisture
		Bulb 1	Bulb 2	Average	
1	12:25	39.2	39.5		
2	12:26	38.2	38.5		
3	12:27	38.1	38.5		
4	12:28	38.4	38.4		
5	12:29	38.5	38.9		
6	12:31	38.7	39.0		
7	12:32	38.8	39.2		
8	12:34	38.6	38.9		
9	12:35	38.7	38.7		
10	12:36	38.6	38.9		
11	12:37	38.9	41.1		
12	12238	39.1	40.0		
13	12:39	39.1	38.5		
14	12:40	39.5	40.5		
15	12:41	39.4	39.7		
16	12:42	40.0	39.8		
17	12:43	39.1	39.2		
18	12:45	38.7	39.1		
19	12:47	38.8	39.0		
20	12:48	38.4	39.2		
21	12:49	38.1	38.4		
22	12:50	38.7	38.8		
23	12:51	38.6	38.9		
24	12:52	39.1	40.0		
25	12:53	39.1	39.8		
26	12:54	39.2	39.7		
27	12:55	40.0	40.1		
28	12:56	39.6	39.8		
29	12:57	39.2	39.7		
30	12:58	39.1	39.5		
31	12:59	38.9	39.2		
32	1:09 (PM)	38.8	39.1		
33	1:01	38.7	38.9		
34	1:02	39.0	39.2		
35	1:03	39.1	39.1		
36	1:04	39.2	39.5		
37	1:17	38.7	39.1		
38	1:06	38.8	38.9		

39	1:10	38.0	39.0		
40	1:12	39.8	39.6		
41	1:13	38.9	39.1		
42	1:14	38.6	38.9		
43	1:15	38.1	39.1		
44	1:17	38.5	38.7		
45	1:18	39.1	39.2		
46	1:19	38.9	39.1		
47	1:20	38.8	39.2		
48	1:21	39.2	39.4		
49	1:22	38.2	38.5		
50	1:24	38.4	39.1		
51	1:25	38.9	39.5		
52					
53					
54					
55					
56					
57					
58					
59					
60					

Compliance Test Active Monitoring
Cook Facility

Run #/Desc.	ARV Test #1

Sample Number	Time	ΔP	Temperature (°F)
1	11:25 am	.06	96
2	11:26 am	.06	96
3	11:27 am	.06	96
4	11:28 am	.06	96
5	11:29 am	.06	96
6	11:30 am	.06	96
7	11:31 am	.06	96
8	11:32 am	.06	96
9	11:33 am	.06	96
10	11:34 am	.06	96
11	11:35 am	.06	96
12	11:36 am	.06	96
13	11:37 am	.06	96
14	11:38 am	.06	96
15	11:39 am	.06	97
16	11:40 am	.06	97
17	11:41 am	.06	97
18	11:42 am	.06	97
19	11:43 am	.06	97
20	11:44 am	.06	98
21	11:45 am	.06	97
22	11:46 am	.06	97
23	11:47 am	.06	97
24	11:48 am	.06	97
25	11:49 am	.06	96
26	11:50 am	.06	96
27	11:51 am	.06	96
28	11:52 am	.06	96
29	11:53 am	.06	96
30	11:54 am	.06	96
31	11:55 am	.06	96
32	11:56 am	.06	96
33	11:57 am	.06	96
34	11:58 am	.06	96
35	11:59 am	.06	96
36	12:00 pm	.06	96
37	12:01 pm	.06	96
38	12:02 pm	.06	96

Test Witness: Jason B Thomas
Jason B Thomas 7/27/2018

39	12:03 PM		96
40	12:04 PM		96
41	12:05 PM		96
42	12:06 PM		96
43	12:07 PM		96
44	12:08 PM		96
45	12:09 PM		96
46	12:10 PM		96
47	12:11 PM		96
48	12:12 PM		96
49	12:13 PM		96
50	12:14 PM		96
51	12:15 PM		96
52	12:16 PM		96
53	12:17 PM		96
54	12:18 PM		96
55	12:19 PM		96
56	12:20 PM		96
57	12:21 PM		96
58	12:22 PM		96
59	12:23 PM		97
60	12:24 PM		97

Compliance Test Active Monitoring
Cook Facility

Run #/Desc.	ARV Test #2

Sample Number	Time	ΔP	Temperature
1	12:25 pm	.06	97
2	12:26 pm	.06	97
3	12:27 pm	.06	97
4	12:28 pm	.06	97
5	12:29 pm	.06	97
6	12:30 pm	.06	97
7	12:31 pm	.06	97
8	12:32 pm	.06	97
9	12:33 pm	.06	97
10	12:34 pm	.06	97
11	12:35 pm	.06	97
12	12:36 pm	.06	97
13	12:37 pm	.06	97
14	12:38 pm	.06	97
15	12:39 pm	.06	97
16	12:40 pm	.06	97
17	12:41 pm	.06	97
18	12:42 pm	.06	97
19	12:43 pm	.06	97
20	12:44 pm	.06	97
21	12:45 pm	.06	97
22	12:46 pm	.06	97
23	12:47 pm	.06	97
24	12:48 pm	.06	97
25	12:49 pm	.06	97
26	12:50 pm	.06	97
27	12:51 pm	.06	97
28	12:52 pm	.06	97
29	12:53 pm	.06	97
30	12:54 pm	.06	97
31	12:55 pm	.06	98
32	12:56 pm	.06	98
33	12:57 pm	.06	98
34	12:58 pm	.06	98
35	12:59 pm	.06	98
36	1:00 pm	.06	98
37	1:01 pm	.06	98
38	1:02 pm	.06	98

Test Witness: Sara B Thomas

Sara B Thomas 1/27/2018

39	1:03 pm	.06	98
40	1:04 pm	.06	98
41	1:05 pm	.06	98
42	1:06 pm	.06	98
43	1:07 pm	.06	98
44	1:08 pm	.06	98
45	1:09 pm	.06	98
46	1:10 pm	.06	98
47	1:11 pm	.06	98
48	1:12 pm	.06	98
49	1:13 pm	.06	98
50	1:14 pm	.06	98
51	1:15 pm	.06	98
52	1:16 pm	.06	98
53	1:17 pm	.06	98
54	1:18 pm	.06	98
55	1:19 pm	.06	98
56	1:20 pm	.06	98
57	1:21 pm	.06	98
58	1:22 pm	.06	98
59	1:23 pm	.06	98
60	1:24 pm	.06	98

Compliance Test Active Monitoring
Cook Facility

Run #/Desc.	ARV Test #3

Sample Number	Time	ΔP	Temperature
1	1:25 pm	.06	98
2	1:26 pm	.06	98
3	1:27 pm	.06	98
4	1:28 pm	.06	98
5	1:29 pm	.06	98
6	1:30 pm	.06	97
7	1:31 pm	.06	97
8	1:32 pm	.06	97
9	1:33 pm	.06	97
10	1:34 pm	.06	97
11	1:35 pm	.06	97
12	1:36 pm	.06	97
13	1:37 pm	.06	97
14	1:38 pm	.06	97
15	1:39 pm	.06	97
16	1:40 pm	.06	97
17	1:41 pm	.06	97
18	1:42 pm	.06	97
19	1:43 pm	.06	97
20	1:44 pm	.06	97
21	1:45 pm	.06	97
22	1:46 pm	.06	97
23	1:47 pm	.06	97
24	1:48 pm	.06	97
25	1:49 pm	.06	97
26	1:50 pm	.06	97
27	1:51 pm	.06	97
28	1:52 pm	.06	97
29	1:53 pm	.06	97
30	1:54 pm	.06	97
31	1:55 pm	.06	97
32	1:56 pm	.06	97
33	1:57 pm	.06	97
34	1:58 pm	.06	97
35	1:59 pm	.06	97
36	2:00 pm	.06	97
37	2:01 pm	.06	97
38	2:02 pm	.06	97

Test Witness: Simon B Thomas
Simon B Thomas 7/27/2018

39	2:03 pm	.06	97
40	2:04 pm	.06	97
41	2:05 pm	.06	97
42	2:06 pm	.06	97
43	2:07 pm	.06	97
44	2:08 pm	.06	97
45	2:09 pm	.06	97
46	2:10 pm	.06	97
47	2:11 pm	.06	97
48	2:12 pm	.06	97
49	2:13 pm	.06	97
50	2:14 pm	.06	97
51	2:15 pm	.06	97
52	2:16 pm	.06	97
53	2:17 pm	.06	97
54	2:18 pm	.06	97
55	2:19 pm	.06	97
56	2:20 pm	.06	97
57	2:21 pm	.06	97
58	2:22 pm	.06	97
59	2:23 pm	.06	97
60	2:24 pm	.06	97

APPENDIX B

SIGNIFICANT FESOP PERMIT REVISION (F 105-32055-00030)

Confidential Business Information

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
Toll Free (800) 451-6027
www.idem.IN.gov

TO: Interested Parties / Applicant

DATE: September 7, 2012

RE: Cook Incorporated / 105 - 32055 - 00030

FROM: Matthew Stuckey, Branch Chief
Permits Branch
Office of Air Quality

Notice of Decision: Approval - Effective Immediately

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to IC 13-15-5-3, this permit is effective immediately, unless a petition for stay of effectiveness is filed and granted according to IC 13-15-6-3, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

If you wish to challenge this decision, IC 4-21.5-3 and IC 13-15-6-1 require that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Suite N 501E, Indianapolis, IN 46204, **within eighteen (18) calendar days of the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

(1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
(2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
(3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

(1) the name and address of the person making the request;
(2) the interest of the person making the request;
(3) identification of any persons represented by the person making the request;
(4) the reasons, with particularity, for the request;
(5) the issues, with particularity, proposed for considerations at any hearing; and
(6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
FNPER.dot12/03/07

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
Toll Free (800) 451-6027
www.idem.IN.gov

September 7, 2012

Larry Price
Cook Medical
PO Box 489
Bloomington, IN 47402

Re: 105-32055-00030
Second Significant Revision to
F105-27381-00030

Dear Mr. Price:

Cook Incorporated was issued a Federally Enforceable State Operating Permit (FESOP) Renewal No. F105-27381-00030 on August 24, 2009 for a stationary medical device manufacturing and sterilization operation located at 6330 North Matthews Drive, Ellettsville, Indiana 47429. On June 27, 2012, the Office of Air Quality (OAQ) received an application from the source requesting a permit modification to include two (2) new ethylene oxide sterilization chambers. The attached Technical Support Document (TSD) provides additional explanation of the changes to the source/permit. Pursuant to the provisions of 326 IAC 2-8-11.1, these changes to the permit are required to be reviewed in accordance with the Significant Permit Revision (SPR) procedures of 326 IAC 2-8-11.1(f). Pursuant to the provisions of 326 IAC 2-8-11.1, a significant permit revision to this permit is hereby approved as described in the attached Technical Support Document (TSD).

The following construction conditions are applicable to the proposed project:

1. General Construction Conditions
The data and information supplied with the application shall be considered part of this source modification approval. Prior to any proposed change in construction which may affect the potential to emit (PTE) of the proposed project, the change must be approved by the Office of Air Quality (OAQ).

2. This approval to construct does not relieve the permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

3. Effective Date of the Permit
Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

4. Pursuant to 326 IAC 2-1.1-9 (Revocation), the Commissioner may revoke this approval if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.

5. All requirements and conditions of this construction approval shall remain in effect unless modified in a manner consistent with procedures established pursuant to 326 IAC 2.

Pursuant to 326 IAC 2-8-11.1, this permit shall be revised by incorporating the significant permit revision into the permit. All other conditions of the permit shall remain unchanged and in effect. Attached please find the entire revised permit.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter, please contact Sarah Street, of my staff, at 317-232-8427 or 1-800-451-6027, and ask for extension 2-8427.

Sincerely,

Iryn Calilung, Section Chief
Permits Branch
Office of Air Quality

Attachments: Technical Support Document and revised permit

IC/ss

cc: File - Monroe County
Monroe County Health Department
U.S. EPA, Region V
Compliance and Enforcement Branch
Billing, Licensing and Training Section

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
We Protect Hoosiers and Our Environment.

Mitchell E. Daniels Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
Toll Free (800) 451-6027
www.idem.IN.gov

Federally Enforceable State Operating Permit Renewal
OFFICE OF AIR QUALITY

Cook Incorporated
6330 North Matthews Drive
Ellettsville, Indiana 47429

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this permit.

The Permittee must comply with all conditions of this permit. Noncompliance with any provisions of this permit is grounds for enforcement action; permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. An emergency does constitute an affirmative defense in an enforcement action provided the Permittee complies with the applicable requirements set forth in Section B, Emergency Provisions.

This permit is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-8 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Indiana statutes from IC 13 and rules from 326 IAC, quoted in conditions in this permit, are those applicable at the time the permit was issued. The issuance or possession of this permit shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a FESOP under 326 IAC 2-8.

Operation Permit No.: F105-27381-00030	
Issued by/Original Signed by: Alfred C. Dumaual, Ph. D., Section Chief Permits Branch Office of Air Quality	Issuance Date: August 24, 2009 Expiration Date: August 24, 2019

First Significant Permit Revision No.: 105-29042-00030, issued June 25, 2010
Interim Significant Permit Revision No.: 105-32055i-00030, issued July 25, 2012

Second Significant Permit Revision No.: F105-32055-00030	
Issued by: Iryn Calilung, Section Chief Permits Branch Office of Air Quality	Issuance Date: September 7, 2012 Expiration Date: August 24, 2019

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SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 through A.3 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-8-3(b)]

The Permittee owns and operates a stationary medical device manufacturing and sterilization operation.

Source Address:	6330 North Matthews Drive, Ellettsville, Indiana 47429
General Source Phone Number:	(800) 468-1379
SIC Code:	3841(Surgical and Medical Instruments and Apparatus)
County Location:	Monroe
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Federally Enforceable State Operating Permit Program Minor Source, under PSD and Emission Offset Rules Minor Source, Section 112 of the Clean Air Act Not 1 of 28 Source Categories

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-8-3(c)(3)]

This stationary source consists of the following emission units and pollution control devices:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to Stacks CEV01 and CEV02, respectively, using no control;

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

Under 40 CFR 63, Subpart O, emission units (a), (b), and (c) listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

(d) Miscellaneous cleaning with isopropyl alcohol (IPA).

(e) One (1) diesel-fired emergency generator, identified as Unit #1, installed on July 31, 2003 and approved for construction in 2010, with a maximum capacity of 1850 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

(f) One (1) diesel-fired emergency generator, identified as Unit #2, installed on November 19, 2003 and approved for construction in 2010, with a maximum capacity of 2922 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

A.3 Insignificant Activities [326 IAC 2-7-1(21)][326 IAC 2-8-3(c)(3)(I)]

This stationary source also includes the following insignificant activities:

(a) One (1) manual plastic tubing and metal wiring slip coating operation, consisting of five trays using a maximum total of 0.033 gallons of coating per hour, exhausting through one (1) stack, identified as E07;

(b) The following storage containers:

(1) nine (9) 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (3,600 pounds total). These are portable cylinders that will be connected to the sterilization process;

(2) nine (9) 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide on standby for connection to the sterilization process as cylinders are emptied;

(3) up to four (4) additional 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide to be stored on site;

(c) Three (3) liquor storage tanks, identified as Tanks A, B, and C, each with a working storage capacity of 5,870 gallons, all venting to the wet acid pre-scrubber, exhausting through one (1) stack, identified as HV01;

(d) Gluing, heat forming, tapering, marking and printing operations associated with manufacturing activities and product assembly, exhausting through building exhausts and one (1) stack, identified as S10;

(e) Natural gas fired combustion sources with a total heat input of 20.45 MMBtu per hour, including the following:

(1) One natural gas-fired boiler, identified as C238-F, constructed in 2000, with a maximum heat input capacity of 0.45 MMBtu per hour;

(2) One natural gas-fired boiler, identified as C240-F, constructed in 2003, with a maximum heat input capacity of 1.26 MMBtu per hour;

(3) One natural gas-fired boiler, identified as C241-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(4) One natural gas-fired boiler, identified as C242-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(5) One natural gas-fired boiler, identified as C239-F, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu per hour;

(6) One natural gas-fired boiler, identified as C246-F, constructed in 2004, with a

maximum heat input capacity of 1.5 MMBtu per hour;

(7) One natural gas-fired boiler, identified as C230-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(8) One natural gas-fired boiler, identified as C231-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(9) One natural gas-fired boiler, identified as C232-F, constructed in 2006, with a maximum heat input capacity of 7.0 MMBtu per hour;

(10) One natural gas-fired boiler, identified as C233-F, constructed in 2006, with a maximum heat input capacity of 0.85 MMBtu per hour;

(11) One natural gas-fired boiler, identified as C364-F, constructed in 2010, with a maximum heat input capacity of 0.5 MMBtu per hour;

(f) Vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids;

(g) Application of oils, greases, lubricants, or other nonvolatile materials applied as temporary protective coatings;

(h) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment; [326 IAC 6-3-2]

(i) Closed loop heating and cooling systems;

(j) Exposure chambers (“towers”, “columns”), for curing of ultra-violet inks and ultra-violet coatings where heat is the intended discharge;

(k) Replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment;

(l) Heat exchanger cleaning and repair;

(m) TDMAC package prep operations, exhausting through one (1) stack, identified as S07;

(n) Heat forming, taping, masking, and printing operations exhausting through various building exhausts;

(o) Catheter Impregnation Process consisting of the following:

(1) A total of six (6) immersion tanks in one (1) immersion booth, with two (2) wells per tank for a total of twelve (12) wells, each well with a capacity of 2880 cubic inches per tank and a weekly usage six (6) liters of solvent and antibiotic solution;

(2) A total of four (4) silicon or polyurethane tubes drying booths; and

(3) A total of one (1) formulation booth, where the immersion solution is mixed.

with potential single HAP (Methanol) emissions of 0.12 tons per year and potential VOC emission of 0.90 tons per year; and

(p) Paclitaxel Treatment Process consisting of the following:

(1) One (1) raw materials mix hood; and

(2) Two (2) Paclitaxel treatment booths.

with potential VOC emissions of less than 15 pounds per day for each booth.

A.4 FESOP Applicability [326 IAC 2-8-2]

This stationary source, otherwise required to have a Part 70 permit as described in 326 IAC 2-7-2(a), has applied to the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) to renew a Federally Enforceable State Operating Permit (FESOP).

SECTION B GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-8-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-7) shall prevail.

B.2 Permit Term [326 IAC 2-8-4(2)][326 IAC 2-1.1-9.5][IC 13-15-3-6(a)]

(a) This permit, F105-27381-000030, is issued for a fixed term of ten (10) years from the issuance date of this permit, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date of this permit.

(b) If IDEM, OAQ, upon receiving a timely and complete renewal permit application, fails to issue or deny the permit renewal prior to the expiration date of this permit, this existing permit shall not expire and all terms and conditions shall continue in effect, until the renewal permit has been issued or denied.

B.3 Term of Conditions [326 IAC 2-1.1-9.5]

Notwithstanding the permit term of a permit to construct, a permit to operate, or a permit modification, any condition established in a permit issued pursuant to a permitting program approved in the state implementation plan shall remain in effect until:

(a) the condition is modified in a subsequent permit action pursuant to Title I of the Clean Air Act; or

(b) the emission unit to which the condition pertains permanently ceases operation.

B.4 Enforceability [326 IAC 2-8-6][IC 13-17-12]

Unless otherwise stated, all terms and conditions in this permit, including any provisions designed to limit the source's potential to emit, are enforceable by IDEM, the United States Environmental Protection Agency (U.S. EPA) and by citizens in accordance with the Clean Air Act.

B.5 Severability [326 IAC 2-8-4(4)]

The provisions of this permit are severable; a determination that any portion of this permit is invalid shall not affect the validity of the remainder of the permit.

B.6 Property Rights or Exclusive Privilege [326 IAC 2-8-4(5)(D)]

This permit does not convey any property rights of any sort or any exclusive privilege.

B.7 Duty to Provide Information [326 IAC 2-8-4(5)(E)]

(a) The Permittee shall furnish to IDEM, OAQ, within a reasonable time, any information that IDEM, OAQ may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. Upon request, the Permittee shall also furnish to IDEM, OAQ copies of records required to be kept by this permit.

(b) For information furnished by the Permittee to IDEM, OAQ, the Permittee may include a claim of confidentiality in accordance with 326 IAC 17.1. When furnishing copies of requested records directly to U. S. EPA, the Permittee may assert a claim of confidentiality in accordance with 40 CFR 2, Subpart B.

B.8 Certification [326 IAC 2-8-3(d)][326 IAC 2-8-4(3)(C)(i)][326 IAC 2-8-5(1)]

(a) A certification required by this permit meets the requirements of 326 IAC 2-8-5(a)(1) if:

(1) it contains a certification by an "authorized individual", as defined by 326 IAC 2-1.1-1(1), and

(2) the certification states that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

(b) The Permittee may use the attached Certification Form, or its equivalent with each submittal requiring certification. One (1) certification may cover multiple forms in one (1) submittal.

(c) An "authorized individual" is defined at 326 IAC 2-1.1-1(1).

B.9 Annual Compliance Certification [326 IAC 2-8-5(a)(1)]

(a) The Permittee shall annually submit a compliance certification report which addresses the status of the source's compliance with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. All certifications shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(b) The annual compliance certification report required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(c) The annual compliance certification report shall include the following:

(1) The appropriate identification of each term or condition of this permit that is the basis of the certification;

(2) The compliance status;

(3) Whether compliance was continuous or intermittent;

(4) The methods used for determining the compliance status of the source, currently and over the reporting period consistent with 326 IAC 2-8-4(3); and

(5) Such other facts, as specified in Sections D of this permit, as IDEM, OAQ may require to determine the compliance status of the source.

The submittal by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

B.10 Compliance Order Issuance [326 IAC 2-8-5(b)]

IDEM, OAQ may issue a compliance order to this Permittee upon discovery that this permit is in nonconformance with an applicable requirement. The order may require immediate compliance or contain a schedule for expeditious compliance with the applicable requirement.

B.11 Preventive Maintenance Plan [326 IAC 1-6-3][326 IAC 2-8-4(9)]

(a) A Preventive Maintenance Plan meets the requirements of 326 IAC 1-6-3 if it includes, at a minimum:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

The Permittee shall implement the PMPs.

(b) If required by specific condition(s) in Section D of this permit where no PMP was previously required, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) no later than ninety (90) days after issuance of this permit or ninety (90) days after initial start-up, whichever is later, including the following information on each facility:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

The PMP extension notification does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

The Permittee shall implement the PMPs.

(c) A copy of the PMPs shall be submitted to IDEM, OAQ upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ may require the Permittee to revise its PMPs whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions. The PMPs and their submittal do not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(d) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

B.12 Emergency Provisions [326 IAC 2-8-12]

(a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation except as provided in 326 IAC 2-8-12.

(b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a health-based or technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:

(1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;

(2) The permitted facility was at the time being properly operated;

(3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;

(4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, or Southeast Regional Office within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

Telephone Number: 1-800-451-6027 (ask for Office of Air Quality, Compliance and Enforcement Branch), or
Telephone Number: 317-233-0178 (ask for Office of Air Quality, Compliance and Enforcement Branch)
Facsimile Number: 317-233-6865
Southeast Regional Office phone: (812) 358-2027; fax: (812) 358-2058.

(5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-8-4(3)(C)(ii) and must contain the following:

(A) A description of the emergency;

(B) Any steps taken to mitigate the emissions; and

(C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(6) The Permittee immediately took all reasonable steps to correct the emergency.

(c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.

(d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.

(e) The Permittee seeking to establish the occurrence of an emergency shall make records available upon request to ensure that failure to implement a PMP did not cause or contribute to an exceedance of any limitations on emissions. However, IDEM, OAQ may require that the Preventive Maintenance Plans required under 326 IAC 2-8-3(c)(6) be revised in response to an emergency.

(f) Failure to notify IDEM, OAQ by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-8 and any other applicable rules.

(g) Operations may continue during an emergency only if the following conditions are met:

(1) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.

(2) If an emergency situation causes a deviation from a health-based limit, the Permittee may not continue to operate the affected emissions facilities unless:

(A) The Permittee immediately takes all reasonable steps to correct the emergency situation and to minimize emissions; and

(B) Continued operation of the facilities is necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw material of substantial economic value.

Any operations shall continue no longer than the minimum time required to prevent the situations identified in (g)(2)(B) of this condition.

B.13 Prior Permits Superseded [326 IAC 2-1.1-9.5]

(a) All terms and conditions of permits established prior to F105-27381-000030 and issued pursuant to permitting programs approved into the state implementation plan have been either:

(1) incorporated as originally stated,

(2) revised, or

(3) deleted.

(b) All previous registrations and permits are superseded by this permit.

B.14 Termination of Right to Operate [326 IAC 2-8-9][326 IAC 2-8-3(h)]

The Permittee's right to operate this source terminates with the expiration of this permit unless a timely and complete renewal application is submitted at least nine (9) months prior to the date of expiration of the source's existing permit, consistent with 326 IAC 2-8-3(h) and 326 IAC 2-8-9.

B.15 Permit Modification, Reopening, Revocation and Reissuance, or Termination [326 IAC 2-8-4(5)(C)][326 IAC 2-8-7(a)][326 IAC 2-8-8]

(a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a Federally Enforceable State Operating Permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any condition of this permit. [326 IAC 2-8-4(5)(C)] The notification by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAQ determines any of the following:

(1) That this permit contains a material mistake.

(2) That inaccurate statements were made in establishing the emissions standards or other terms or conditions.

(3) That this permit must be revised or revoked to assure compliance with an applicable requirement. [326 IAC 2-8-8(a)]

(c) Proceedings by IDEM, OAQ to reopen and revise this permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of this permit for which cause to reopen exists. Such reopening and revision shall be made as expeditiously as practicable. [326 IAC 2-8-8(b)]

(d) The reopening and revision of this permit, under 326 IAC 2-8-8(a), shall not be initiated before notice of such intent is provided to the Permittee by IDEM, OAQ at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAQ may provide a shorter time period in the case of an emergency. [326 IAC 2-8-8(c)]

B.16 Permit Renewal [326 IAC 2-8-3(h)]

(a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAQ and shall include the information specified in 326 IAC 2-8-3. Such information shall be included in the application for each emission unit at this source, except those emission units included on the trivial or insignificant activities list contained in 326 IAC 2-7-1(21) and 326 IAC 2-7-1(40). The renewal application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(b) A timely renewal application is one that is:

(1) Submitted at least nine (9) months prior to the date of the expiration of this permit; and

(2) If the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(c) If the Permittee submits a timely and complete application for renewal of this permit, the source's failure to have a permit is not a violation of 326 IAC 2-8 until IDEM, OAQ takes final action on the renewal application, except that this protection shall cease to apply if, subsequent to the completeness determination, the Permittee fails to submit by the deadline specified, pursuant to 326 IAC 2-8-3(g), in writing by IDEM, OAQ any additional information identified as being needed to process the application.

B.17 Permit Amendment or Revision [326 IAC 2-8-10][326 IAC 2-8-11.1]

(a) Permit amendments and revisions are governed by the requirements of 326 IAC 2-8-10 or 326 IAC 2-8-11.1 whenever the Permittee seeks to amend or modify this permit.

(b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

Any such application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.18 Operational Flexibility [326 IAC 2-8-15][326 IAC 2-8-11.1]

(a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-8-15(b) and (c) without a prior permit revision, if each of the following conditions is met:

(1) The changes are not modifications under any provision of Title I of the Clean Air Act;

(2) Any approval required by 326 IAC 2-8-11.1 has been obtained;

(3) The changes do not result in emissions which exceed the limitations provided in this permit (whether expressed herein as a rate of emissions or in terms of total emissions);

(4) The Permittee notifies the:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue

MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Regulation Development Branch - Indiana (AR-18J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

in advance of the change by written notification at least ten (10) days in advance of the proposed change. The Permittee shall attach every such notice to the Permittee's copy of this permit; and

(5) The Permittee maintains records on-site, on a rolling five (5) year basis, which document all such changes and emission trades that are subject to 326 IAC 2-8-15(b)(1) and (c). The Permittee shall make such records available, upon reasonable request, for public review.

Such records shall consist of all information required to be submitted to IDEM, OAQ in the notices specified in 326 IAC 2-8-15(b)(1) and (c).

(b) Emission Trades [326 IAC 2-8-15(b)]
The Permittee may trade emissions increases and decreases at the source, where the applicable SIP provides for such emission trades without requiring a permit revision, subject to the constraints of Section (a) of this condition and those in 326 IAC 2-8-15(c).

(c) Alternative Operating Scenarios [326 IAC 2-8-15(c)]
The Permittee may make changes at the source within the range of alternative operating scenarios that are described in the terms and conditions of this permit in accordance with 326 IAC 2-8-4(7). No prior notification of IDEM, OAQ, or U.S. EPA is required.

(d) Backup fuel switches specifically addressed in, and limited under, Section D of this permit shall not be considered alternative operating scenarios. Therefore, the notification requirements of part (a) of this condition do not apply.

B.19 Source Modification Requirement [326 IAC 2-8-11.1]

A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2.

B.20 Inspection and Entry [326 IAC 2-8-5(a)(2)][IC 13-14-2-2][IC 13-17-3-2][IC 13-30-3-1]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee's right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

(a) Enter upon the Permittee's premises where a FESOP source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;

(b) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

(c) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, inspect, at reasonable times, any facilities, equipment (including monitoring and air

pollution control equipment), practices, or operations regulated or required under this permit;

(d) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and

(e) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.21 Transfer of Ownership or Operational Control [326 IAC 2-8-10]

(a) The Permittee must comply with the requirements of 326 IAC 2-8-10 whenever the Permittee seeks to change the ownership or operational control of the source and no other change in the permit is necessary.

(b) Any application requesting a change in the ownership or operational control of the source shall contain a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current and new Permittee. The application shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

Any such application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.22 Annual Fee Payment [326 IAC 2-7-19][326 IAC 2-8-4(6)][326 IAC 2-8-16][326 IAC 2-1.1-7]

(a) The Permittee shall pay annual fees to IDEM, OAQ no later than thirty (30) calendar days of receipt of a billing. Pursuant to 326 IAC 2-7-19(b), if the Permittee does not receive a bill from IDEM, OAQ the applicable fee is due April 1 of each year.

(b) Failure to pay may result in administrative enforcement action or revocation of this permit.

(c) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-4230 (ask for OAQ, Billing, Licensing, and Training Section), to determine the appropriate permit fee.

B.23 Credible Evidence [326 IAC 2-8-4(3)][326 IAC 2-8-5][62 FR 8314][326 IAC 1-1-6]

For the purpose of submitting compliance certifications or establishing whether or not the Permittee has violated or is in violation of any condition of this permit, nothing in this permit shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether the Permittee would have been in compliance with the condition of this permit if the appropriate performance or compliance test or procedure had been performed.

SECTION C SOURCE OPERATION CONDITIONS

Entire Source

Emission Limitations and Standards [326 IAC 2-8-4(1)]

C.1 Particulate Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) Pounds per Hour [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2(e)(2), particulate emissions from any process not exempt under 326 IAC 6-3-1(b) or (c) which has a maximum process weight rate less than 100 pounds per hour and the methods in 326 IAC 6-3-2(b) through (d) do not apply shall not exceed 0.551 pounds per hour.

C.2 Overall Source Limit [326 IAC 2-8]

The purpose of this permit is to limit this source's potential to emit to less than major source levels for the purpose of Section 502(a) of the Clean Air Act.

(a) Pursuant to 326 IAC 2-8:

(1) The potential to emit any regulated pollutant, except particulate matter (PM) and greenhouse gases (GHGs), from the entire source shall be limited to less than one hundred (100) tons per twelve (12) consecutive month period.

(2) The potential to emit any individual hazardous air pollutant (HAP) from the entire source shall be limited to less than ten (10) tons per twelve (12) consecutive month period; and

(3) The potential to emit any combination of HAPs from the entire source shall be limited to less than twenty-five (25) tons per twelve (12) consecutive month period.

(4) The potential to emit greenhouse gases (GHGs) from the entire source shall be limited to less than one hundred thousand (100,000) tons of CO2 equivalent emissions (CO2e) per twelve (12) consecutive month period.

(b) Pursuant to 326 IAC 2-2 (PSD), potential to emit particulate matter (PM) from the entire source shall be limited to less than two hundred fifty (250) tons per twelve (12) consecutive month period.

(c) This condition shall include all emission points at this source including those that are insignificant as defined in 326 IAC 2-7-1(21). The source shall be allowed to add insignificant activities not already listed in this permit, provided that the source's potential to emit does not exceed the above specified limits.

(d) Section D of this permit contains independently enforceable provisions to satisfy this requirement.

C.3 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-1 (Applicability) and 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.4 Open Burning [326 IAC 4-1][IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1.

C.5 Incineration [326 IAC 4-2][326 IAC 9-1-2]

The Permittee shall not operate an incinerator except as provided in 326 IAC 4-2 or in this permit. The Permittee shall not operate a refuse incinerator or refuse burning equipment except as provided in 326 IAC 9-1-2 or in this permit.

C.6 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions).

C.7 Asbestos Abatement Projects [326 IAC 14-10][326 IAC 18][40 CFR 61, Subpart M]

(a) Notification requirements apply to each owner or operator. If the combined amount of regulated asbestos containing material (RACM) to be stripped, removed or disturbed is at least 260 linear feet on pipes or 160 square feet on other facility components, or at least thirty-five (35) cubic feet on all facility components, then the notification requirements of 326 IAC 14-10-3 are mandatory. All demolition projects require notification whether or not asbestos is present.

(b) The Permittee shall ensure that a written notification is sent on a form provided by the Commissioner at least ten (10) working days before asbestos stripping or removal work or before demolition begins, per 326 IAC 14-10-3, and shall update such notice as necessary, including, but not limited to the following:

(1) When the amount of affected asbestos containing material increases or decreases by at least twenty percent (20%); or

(2) If there is a change in the following:

(A) Asbestos removal or demolition start date;

(B) Removal or demolition contractor; or

(C) Waste disposal site.

(c) The Permittee shall ensure that the notice is postmarked or delivered according to the guidelines set forth in 326 IAC 14-10-3(2).

(d) The notice to be submitted shall include the information enumerated in 326 IAC 14-10-3(3).

All required notifications shall be submitted to:

Indiana Department of Environmental Management

Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue

MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

The notice shall include a signed certification from the owner or operator that the information provided in this notification is correct and that only Indiana licensed workers and project supervisors will be used to implement the asbestos removal project. The notifications do not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(e) Procedures for Asbestos Emission Control
The Permittee shall comply with the applicable emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-1, emission control requirements are applicable for any removal or disturbance of RACM greater than three (3) linear feet on pipes or three (3) square feet on any other facility components or a total of at least 0.75 cubic feet on all facility components.

(f) Demolition and Renovation
The Permittee shall thoroughly inspect the affected facility or part of the facility where the demolition or renovation will occur for the presence of asbestos pursuant to 40 CFR 61.145(a).

(g) Indiana Licensed Asbestos Inspector
The Permittee shall comply with 326 IAC 14-10-1(a) that requires the owner or operator, prior to a renovation/demolition, to use an Indiana Licensed Asbestos Inspector to thoroughly inspect the affected portion of the facility for the presence of asbestos.

Testing Requirements [326 IAC 2-8-4(3)]

C.8 Performance Testing [326 IAC 3-6]

(a) For performance testing required by this permit, a test protocol, except as provided elsewhere in this permit, shall be submitted to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

no later than thirty-five (35) days prior to the intended test date. The protocol submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14) days prior to the actual test date. The notification submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) Pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by IDEM, OAQ if the Permittee submits to IDEM, OAQ a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

Compliance Requirements [326 IAC 2-1.1-11]

C.9 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements by issuing an order under 326 IAC 2-1.1-11. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

Compliance Monitoring Requirements [326 IAC 2-8-4][326 IAC 2-8-5(a)(1)]

C.10 Compliance Monitoring [326 IAC 2-8-4(3)][326 IAC 2-8-5(a)(1)]

Unless otherwise specified in this permit, for all monitoring requirements not already legally required, the Permittee shall be allowed up to ninety (90) days from the date of permit issuance or of initial start-up, whichever is later, to begin such monitoring. If due to circumstances beyond the Permittee's control, any monitoring equipment required by this permit cannot be installed and operated no later than ninety (90) days after permit issuance or the date of initial startup, whichever is later, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Unless otherwise specified in the approval for the new emission unit(s), compliance monitoring for new emission units or emission units added through a permit revision shall be implemented when operation begins.

C.11 Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-8-4(3)][326 IAC 2-8-5(1)]

(a) When required by any condition of this permit, an analog instrument used to measure a parameter related to the operation of an air pollution control device shall have a scale such that the expected maximum reading for the normal range shall be no less than twenty percent (20%) of full scale.

(b) The Permittee may request that the IDEM, OAQ approve the use of an instrument that does not meet the above specifications provided the Permittee can demonstrate that an alternative instrument specification will adequately ensure compliance with permit conditions requiring the measurement of the parameters.

Corrective Actions and Response Steps [326 IAC 2-8-4][326 IAC 2-8-5(a)(1)]

C.12 Risk Management Plan [326 IAC 2-8-4][40 CFR 68]

If a regulated substance, as defined in 40 CFR 68, is present at a source in more than a threshold quantity, the Permittee must comply with the applicable requirements of 40 CFR 68.

C.13 Response to Excursions or Exceedances [326 IAC 2-8-4][326 IAC 2-8-5]

Upon detecting an excursion where a response step is required by the D Section or an exceedance of a limitation in this permit:

(a) The Permittee shall take reasonable response steps to restore operation of the emissions unit (including any control device and associated capture system) to its normal or usual manner of operation as expeditiously as practicable in accordance with good air pollution control practices for minimizing excess emissions.

(b) The response shall include minimizing the period of any startup, shutdown or malfunction. The response may include, but is not limited to, the following:

(1) initial inspection and evaluation;

(2) recording that operations returned or are returning to normal without operator action (such as through response by a computerized distribution control system); or

(3) any necessary follow-up actions to return operation to normal or usual manner of operation.

(c) A determination of whether the Permittee has used acceptable procedures in response to an excursion or exceedance will be based on information available, which may include, but is not limited to, the following:

(1) monitoring results;

(2) review of operation and maintenance procedures and records; and/or

(3) inspection of the control device, associated capture system, and the process.

(d) Failure to take reasonable response steps shall be considered a deviation from the permit.

(e) The Permittee shall record the reasonable response steps taken.

C.14 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-8-4][326 IAC 2-8-5]

(a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall submit a description of its response actions to IDEM, OAQ, no later than seventy-five (75) days after the date of the test.

(b) A retest to demonstrate compliance shall be performed no later than one hundred eighty (180) days after the date of the test. Should the Permittee demonstrate to IDEM, OAQ that retesting in one hundred eighty (180) days is not practicable, IDEM, OAQ may extend the retesting deadline

(c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

The response action documents submitted pursuant to this condition do require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Record Keeping and Reporting Requirements [326 IAC 2-8-4(3)]

C.15 General Record Keeping Requirements [326 IAC 2-8-4(3)][326 IAC 2-8-5]

(a) Records of all required monitoring data, reports and support information required by this permit shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. Support information includes the following:

(AA) All calibration and maintenance records.
(BB) All original strip chart recordings for continuous monitoring instrumentation.
(CC) Copies of all reports required by the FESOP.

Records of required monitoring information include the following:

(AA) The date, place, as defined in this permit, and time of sampling or measurements.
(BB) The dates analyses were performed.
(CC) The company or entity that performed the analyses.
(DD) The analytical techniques or methods used.
(EE) The results of such analyses.
(FF) The operating conditions as existing at the time of sampling or measurement.

These records shall be physically present or electronically accessible at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Unless otherwise specified in this permit, for all record keeping requirements not already legally required, the Permittee shall be allowed up to ninety (90) days from the date of permit issuance or the date of initial start-up, whichever is later, to begin such record keeping.

C.16 General Reporting Requirements [326 IAC 2-8-4(3)(C)][326 IAC 2-1.1-11]

(a) The Permittee shall submit the attached Quarterly Deviation and Compliance Monitoring Report or its equivalent. Proper notice submittal under Section B –Emergency Provisions satisfies the reporting requirements of this paragraph. Any deviation from permit requirements, the date(s) of each deviation, the cause of the deviation, and the response steps taken must be reported except that a deviation required to be reported pursuant to an applicable requirement that exists independent of this permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. This report shall be submitted not later than thirty (30) days after the end of the reporting period. The Quarterly Deviation and Compliance Monitoring Report shall include a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1). A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit.

(b) The address for report submittal is:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(c) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(d) Reporting periods are based on calendar years, unless otherwise specified in this permit. For the purpose of this permit "calendar year" means the twelve (12) month period from January 1 to December 31 inclusive.

Stratospheric Ozone Protection

C.17 Compliance with 40 CFR 82 and 326 IAC 22-1

Pursuant to 40 CFR 82 (Protection of Stratospheric Ozone), Subpart F, except as provided for motor vehicle air conditioners in Subpart B, the Permittee shall comply with applicable standards for recycling and emissions reduction.

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to Stacks CEV01 and CEV02, respectively, using no control;

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

Under 40 CFR 63, Subpart O, emission units (a), (b), and (c) listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.1.1 Ethylene Oxide [326 IAC 8-1-6]

Pursuant to FESOP F105-8436-00030, issued on February 16, 1998, and 326 IAC 8-1-6, the following control technology will also serve as the Best Available Control Technology (BACT) for the sterilization operations S1 through S7. The control technology used to comply with the requirements of 40 CFR 63.360 through 63.367, which apply to the sterilization process, in addition to the following:

(a) A single nonregenerable dry bed reactor to reduce ethylene oxide emissions to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, to control the seven (7) sterilization chamber exhaust vents, identified as units S1 through S7.

(b) A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) with a control efficiency of 99% to control emissions from the fourteen (14) aeration rooms.

The requirements listed above will control ethylene oxide emissions from the sterilization operations S1 through S7 such that ethylene oxide emissions from S1 through S7 shall not exceed 0.38 tons per year.

Since the requirement to operate the dry bed reactor controlling the emissions from the sterilization chamber exhaust vents (back vents) in the original FESOP was also part of the requirements to satisfy 326 IAC 8-1-6 (New Facilities, General Reduction Requirements), the source is still required to operate the dry bed reactor controlling emissions from the sterilization chamber exhaust vents (back vents) for units S1 through S7 in order to comply with 326 IAC 8-1-6,

even though a control for emissions from back vents is not required by NESHAP Subpart O [40 CFR 63.36]; the source is also required to operate the primary wet acid scrubber to control emissions from the sterilization chambers, as well as the wet acid pre-scrubber and three (3) dry bed reactors (in parallel) to control emissions from the fourteen (14) aerations rooms in order to comply with 326 IAC 8-1-6 (New Facilities, General Reduction Requirements).

Note: The source will not be required to operate the dry bed reactor to control emissions from the sterilization chamber exhaust vents (back vents) from the two (2) sterilizers S8 and S9, approved for construction in 2012. S8 and S9 are not subject to the requirements of 326 IAC 8-1-6.

D.1.2 Hazardous Air Pollutants (HAPs) [326 IAC 2-8-4]

Pursuant to 326 IAC 2-8, the total ethylene oxide emissions from the nine (9) ethylene oxide sterilization chambers and the fourteen (14) aeration rooms shall be less than 9.40 tons per twelve (12) consecutive month period, total, with compliance determined at the end of each month

Compliance with the above limit, combined with the potential to emit ethylene oxide from other emission units at the source, shall limit the ethylene oxide from the entire source to less than 10 tons per twelve (12) consecutive month period, total HAPs to less than twenty-five (25) tons per 12 consecutive month period, and render 326 IAC 2-7 (Part 70 Permits) and 326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP) not applicable.

D.1.3 Preventive Maintenance Plan [326 IAC 2-8-4(9)]

A Preventive Maintenance Plan is required for this facility and any control devices. Section B - Preventive Maintenance Plan contains the Permittee's obligation with regard to the preventive maintenance plan required by this condition.

Compliance Determination Requirements [326 IAC 2-8-4] [326 IAC 2-8-5(a)(1)]

D.1.4 Ethylene Oxide Control [326 IAC 8-1-6] [326 IAC 2-8-4]

(a) In order to comply with Conditions D.1.1, and D.1.2, the primary wet acid scrubber and the single non-regenerable dry bed reactor shall be in operation and control emissions from the seven (7) ethylene oxide sterilization chambers S1 through S7 at all times the ethylene oxide sterilization chambers are in operation.

(b) In order to comply with Conditions D.1.1, and D.1.2, the primary wet acid scrubber shall be in operation and control emissions from the two (2) ethylene oxide sterilization chambers S8 and S9 at all times the ethylene oxide sterilization chambers are in operation.

(c) In order to comply with Conditions D.1.1, and D.1.2, the three (3) dry bed reactors with or without the wet acid pre-scrubber shall be in operation and control emissions from the fourteen (14) aeration rooms at all times the fourteen (14) aeration rooms are in operation.

D.1.5 Testing Requirements [326 IAC 2-8-5(a)(1)] [326 IAC 2-1.1-11] [40 CFR Part 63, Subpart O]

In order to demonstrate the compliance status with Condition D.1.1, Condition D.1.2, and Condition E.1.2, not later than 180 days after the startup of sterilization chambers S8 and S9, the Permittee shall perform a performance test on each of the following control devices:

(a) The one (1) primary wet acid scrubber, exhausting to stack PS01, controlling ethylene oxide emissions from the nine (9) sterilization chamber S1 through S9;

(b) The one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), exhausting to stack HV01, controlling ethylene oxide emissions from the fourteen (14) aeration rooms;

using the procedures listed in 40 CFR 63.7 of Subpart A, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. During the performance test, the owner or operator shall determine the efficiency of the control devices and the site-specific operating parameters for each of the wet acid scrubbers and the dry bed reactors. This test shall be repeated at least once every five (5) years the date of the most recent valid compliance demonstration. Testing shall be conducted in accordance with the provisions of 326 IAC 3-6 (Source Sampling Procedures). Section C - Performance Testing contains the Permittee's obligation with regard to the performance testing required by this condition.

Compliance Monitoring Requirements [326 IAC 2-8-4] [326 IAC 2-8-5(a)(1)]

D.1.6 Monitoring

To demonstrate the compliance status with the control efficiency and emission limitations requirements in conditions D.1.1, and D.1.2:

(a) for the single non-regenerable dry bed reactor controlling ethylene oxide emissions from the seven (7) sterilization chamber exhaust vents (back vents) for units S1 through S7, the Permittee shall monitor and record the number of equivalent sterilization cycles performed while the bed is in service.

(b) The Permittee shall keep a record of the number of sterilization cycles run for sterilizer units S1 through S7, convert this to equivalent cycles for a 512 ft^3 sterilizer, and keep a daily running record of total equivalent cycles. Upon reaching 2,917 equivalent sterilization cycles, based on the manufacturer's guaranteed bed capacity of 360 pounds of ethylene oxide, the performance of the dry bed reactor is assumed to drop below 99% removal efficiency and the bed material will have to be removed and replaced with fresh reactant.

Record Keeping and Reporting Requirements [326 IAC 2-8-4(3)] [326 IAC 2-8-16]

D.1.7 Record Keeping Requirements

(a) To document the compliance status with Conditions D.1.1, D.1.2, and D.1.6, the Permittee shall maintain records in accordance with (1) and (2) below. Records maintained for (1) shall be taken daily and shall be complete and sufficient to establish compliance with the ethylene oxide emission limits and/or control efficiency limits established in Conditions D.1.1, and D.1.2, and the monitoring requirements established in Condition D.1.6. Records maintained for (2) shall be taken daily and shall be used for reference purposes only. Records necessary to demonstrate compliance shall be available within 30 days of the end of each compliance period.

(1) The number of equivalent sterilization cycles performed daily while the single non-regenerable dry bed reactor controlling chamber exhaust vents is in service; and

(2) The number of equivalent sterilization cycles performed daily while the three (3) dry bed reactors controlling aeration room exhaust are in service.

(b) Section C - General Record Keeping Requirements, of this permit contains the Permittee's obligations with regard to the records required by this condition.

SECTION D.2 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(h) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment; [326 IAC 6-3-2]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.2.1 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2(e)(2), the particulate emissions from the brazing equipment, cutting torches, soldering equipment and welding equipment shall not exceed 0.551 pound per hour.

SECTION D.3 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(e) Natural gas fired combustion sources with a total heat input of 20.45 MMBtu per hour, including the following:

(1) One natural gas-fired boiler, identified as C238-F, constructed in 2000, with a maximum heat input capacity of 0.45 MMBtu per hour;

(2) One natural gas-fired boiler, identified as C240-F, constructed in 2003, with a maximum heat input capacity of 1.26 MMBtu per hour;

(3) One natural gas-fired boiler, identified as C241-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(4) One natural gas-fired boiler, identified as C242-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(5) One natural gas-fired boiler, identified as C239-F, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu per hour;

(6) One natural gas-fired boiler, identified as C246-F, constructed in 2004, with a maximum heat input capacity of 1.5 MMBtu per hour;

(7) One natural gas-fired boiler, identified as C230-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(8) One natural gas-fired boiler, identified as C231-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(9) One natural gas-fired boiler, identified as C232-F, constructed in 2006, with a maximum heat input capacity of 7.0 MMBtu per hour;

(10) One natural gas-fired boiler, identified as C233-F, constructed in 2006, with a maximum heat input capacity of 0.85 MMBtu per hour;

(11) One natural gas-fired boiler, identified as C364-F, constructed in 2010, with a maximum heat input capacity of 0.5 MMBtu per hour;

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.3.1 Particulate Matter [326 IAC 6-2]

Pursuant to 326 IAC 6-2-4, particulate emissions from each individual boiler shall be limited as follows:

Unit ID	PM Emission Limit (lb/MMBtu)
C238-F	0.6
C240-F	0.6
C241-F	0.6
C242-F	0.6
C239-F	0.6
C246-F	0.6
C230-F	0.5
C231-F	0.5
C232-F	0.5
C233-F	0.5
C364-F	0.5

Particulate emissions from indirect heating facilities constructed after September 21, 1983 shall be limited by the following equation:

$$Pt = \frac{1.09}{Q^{0.26}}$$

Pt = pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input.
Q = Total source maximum operating capacity in MMBtu/hr heat input. Maximum operating capacity is defined as the maximum capacity at which the unit is operated or the nameplate capacity, whichever is specified in the permit application, except when a lower limitation is contained in the facility's operating permit.

SECTION E.1 SOURCE OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to Stacks CEV01 and CEV02, respectively, using no control;

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

Under 40 CFR 63, Subpart O, emission units (a), (b), and (c) listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

National Emission Standards for Hazardous Air Pollutants (NESHAP) Requirements

E.1.1 General Provisions Relating to NESHAP O [326 IAC 20-1][40 CFR Part 63, Subpart A]

The requirements of 40 CFR Part 63, Subpart A – General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facilities described in this section except as otherwise specified in 40 CFR 63, Subpart O.

E.1.2 Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP [40 CFR Part 63, Subpart O] [326 IAC 20-5]

The Permittee which owns or operates stationary ethylene oxide sterilization facility at an area source of HAP emissions shall comply with the following provisions of 40 CFR Part 63, Subpart O as follows:

(1) 40 CFR 63.360,
(2) 40 CFR 63.361,
(3) 40 CFR 63.362,
(4) 40 CFR 63.363(a), (b)(1), (b)(2), (c), (e), (f),
(5) 40 CFR 63.364(a), (b), (d), (e),
(6) 40 CFR 63.365,
(7) 40 CFR 63.366,
(8) 40 CFR 63.367,
(9) 40 CFR 63.368.

SECTION E.2 EMISSIONS UNIT OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(e) One (1) diesel-fired emergency generator, identified as Unit #1, installed on July 31, 2003 and approved for construction in 2010, with a maximum capacity of 1850 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

(f) One (1) diesel-fired emergency generator, identified as Unit #2, installed on November 19, 2003 and approved for construction in 2010, with a maximum capacity of 2922 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

E.2.1 General Provisions Relating to NESHAP ZZZZ [326 IAC 20-1][40 CFR Part 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A – General Provisions, which are incorporated by reference as 326 IAC 20-1-1, apply to the facilities described in this section except when otherwise specified in 40 CFR Part 63, Subpart ZZZZ.

E.2.2 National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines [326 IAC 20-82][40 CFR 63, Subpart ZZZZ]

The Permittee which owns or operates a stationary RICE at an area source of HAP emissions shall comply with the following provisions of 40 CFR Part 63, Subpart ZZZZ:

(1) 40 CFR 63.6580
(2) 40 CFR 63.6585
(3) 40 CFR 63.6590(a)(1)(iii), (b)(3)

The entire text of 40 CFR 63, Subpart ZZZZ is included as Attachment B to this permit.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP) CERTIFICATION

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F105-27381-00030

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this permit.

Please check what document is being certified:

☐ Annual Compliance Certification Letter

☐ Test Result (specify)_____

☐ Report (specify)_____

☐ Notification (specify)_____

☐ Affidavit (specify)_____

☐ Other (specify)_____

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Date:

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE AND ENFORCEMENT BRANCH
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
Phone: (317) 233-0178
Fax: (317) 233-6865

FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
EMERGENCY OCCURRENCE REPORT

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F105-27381-00030

This form consists of 2 pages **Page 1 of 2**

□ This is an emergency as defined in 326 IAC 2-7-1(12)
- The Permittee must notify the Office of Air Quality (OAQ), within four (4) daytime business hours (1-800-451-6027 or 317-233-0178, ask for Compliance Section); and
- The Permittee must submit notice in writing or by facsimile within two (2) working days (Facsimile Number: 317-233-6865), and follow the other requirements of 326 IAC 2-7-16

If any of the following are not applicable, mark N/A

Facility/Equipment/Operation:
Control Equipment:
Permit Condition or Operation Limitation in Permit:
Description of the Emergency:
Describe the cause of the Emergency:

APPENDIX C

TECHNICAL SUPPORT DOCUMENT (TSD) For F 105-32005-00030

Confidential Business Information

Indiana Department of Environmental Management
Office of Air Quality

Addendum to the Technical Support Document (ATSD) for a Significant Permit Revision to a Federally Enforceable State Operating Permit (FESOP)

Source Background and Description

Source Name:	**Cook Incorporated**
Source Location:	**6330 North Matthews Drive, Ellettsville, Indiana 47429**
County:	**Monroe**
SIC Code:	**3841 (Surgical and Medical Instruments and Apparatus)**
Operation Permit No.:	**F105-27381-00030**
Operation Permit Issuance Date:	**August 24, 2009**
Significant Permit Revision No.:	**F105-32055-00030**
Permit Reviewer:	**Sarah Street**

On August 7, 2012, the Office of Air Quality (OAQ) had a notice published in The Herald Times, Bloomington, Indiana, stating that Cook Incorporated had applied for a Significant Permit Revision to add two (2) new ethylene oxide sterilization chambers to an existing stationary medical device manufacturing and sterilization operation. The notice also stated that the OAQ proposed to issue a Significant Permit Revision for this operation and provided information on how the public could review the proposed permit and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this permit should be issued as proposed.

Comments and Responses

No comments were received during the public notice period.

Additional Changes

IDEM, OAQ has decided to make additional revisions to the permit as described below, with deleted language as ~~strikeouts~~ and new language **bolded**.

(a) As a part of editing the insignificant activities, with this revision the ethylene oxide storage containers increased from six (6) to nine (9) (documented in the Technical Support Document); however, the total capacity with the increase of storage containers should have been amended as well.

The permit has been revised as follows:

A.3 Insignificant Activities [326 IAC 2-7-1(21)][326 IAC 2-8-3(c)(3)(I)]

This stationary source also includes the following insignificant activities:

...

(b) The following storage containers:

(1) nine (9) 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (~~2,400~~ **3,600** pounds total). These are portable cylinders that will be connected to the sterilization process;

...

IDEM Contact

(a) Questions regarding this proposed Significant Permit Revision can be directed to Sarah Street at the Indiana Department Environmental Management, Office of Air Quality, Permits Branch, 100 North Senate Avenue, MC 61-53 IGCN 1003, Indianapolis, Indiana 46204-2251 or by telephone at (317) 232-8427 or toll free at 1-800-451-6027 extension 2-8427.

(b) A copy of the permit is available on the Internet at: http://www.in.gov/ai/appfiles/idem-caats/

(c) For additional information about air permits and how the public and interested parties can participate, refer to the IDEM's Guide for Citizen Participation and Permit Guide on the Internet at: www.idem.in.gov

Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD) for a Significant Permit Revision to a Federally Enforceable State Operating Permit (FESOP)

Source Description and Location

Source Name:	**Cook Incorporated**
Source Location:	**6330 North Matthews Drive, Ellettsville, Indiana 47429**
County:	**Monroe**
SIC Code:	**3841 (Surgical and Medical Instruments and Apparatus)**
Operation Permit No.:	**F105-27381-00030**
Operation Permit Issuance Date:	**August 24, 2009**
Significant Permit Revision No.:	**F105-32055-00030**
Permit Reviewer:	**Sarah Street**

On June 27, 2012 the Office of Air Quality (OAQ) received an application from Cook Incorporated related to a modification to an existing stationary medical device manufacturing and sterilization operation.

Existing Approvals

The source was issued FESOP Renewal No. F105-27381-00030 on August 24, 2009. The source has since received the following approvals:

(a) Significant Permit Revision No. 105-29042-00030, issued June 25, 2010.

(b) Interim Significant Permit Revision No. 105-32055i-00030, issued July 25, 2012.

County Attainment Status

The source is located in Monroe County.

Pollutant	Designation
SO_2	Better than national standards.
CO	Unclassifiable or attainment effective November 15, 1990.
O3	Unclassifiable or attainment effective June 15, 2004, for the 8-hour ozone standard.[1]
PM_{10}	Unclassifiable effective November 15, 1990.
NO_2	Cannot be classified or better than national standards.
Pb	Not designated.
[1]Unclassifiable or attainment effective October 18, 2000, for the 1-hour ozone standard which was revoked effective June 15, 2005. Unclassifiable or attainment effective April 5, 2005, for $PM_{2.5}$.	

(a) Ozone Standards

Volatile organic compounds (VOC) and Nitrogen Oxides (NOx) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC and NOx emissions are considered when evaluating the rule applicability relating to ozone. Monroe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(b) $PM_{2.5}$
Monroe County has been classified as attainment for $PM_{2.5}$. On May 8, 2008 U.S. EPA promulgated the requirements for Prevention of Significant Deterioration (PSD) for $PM_{2.5}$ emissions. These rules became effective on July 15, 2008. On May 4, 2011 the air pollution control board issued an emergency rule establishing the direct $PM_{2.5}$ significant level at ten (10) tons per year. This rule became effective, June 28, 2011. Therefore, direct $PM_{2.5}$ and SO_2 emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2. See the State Rule Applicability – Entire Source section.

(c) Other Criteria Pollutants
Monroe County has been classified as attainment or unclassifiable in Indiana for all criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

Fugitive Emissions

Since this type of operation is not one of the twenty-eight (28) listed source categories under 326 IAC 2-2, 326 IAC 2-3, or 326 IAC 2-7, and there is no applicable New Source Performance Standard that was in effect on August 7, 1980, fugitive emissions are not counted toward the determination of PSD, Emission Offset, and Part 70 Permit applicability.

Status of the Existing Source

The table below summarizes the potential to emit of the entire source, prior to the proposed revision, after consideration of all enforceable limits established in the effective permits:

Process/ Emission Unit	Potential To Emit of the Entire Source Prior to Revision (tons/year)									
	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	GHGs as CO_2e**	Total HAPs	Worst Single HAP
Sterilization	-	-	-	-	-	0.38	-	-	0.38	0.38 (ethylene oxide)
Surface Coating	-	-	-	-	-	2.05	-	-	0.01	0.01 (methanol)
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	-	0.12	0.12 (methanol)
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-	-
Boiler	0.09	0.38	0.38	0.03	4.97	0.27	4.17	-	0.09	0.09 (hexane)
Emergency Generators (Unit #1 and Unit #2): Diesel Combustion	0.84	0.84	0.84	4.83	28.63	0.32	-	-	1.25 E-02	6.48E-03 (benzene)
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	-	0.17	0.09 (TCE)
Total PTE of Entire Source	**1.07**	**1.35**	**1.35**	**4.86**	**33.60**	**18.99**	**10.74**	**-**	**0.79**	**0.38 (ethylene oxide)**
Title V Major Source Thresholds**	NA	100	100	100	100	100	100	100,000	25	10
PSD Major Source Thresholds**	250	250	250	250	250	250	250	100,000	NA	NA

negl. = negligible
These emissions are based upon Technical Support Document (TSD) to Significant Permit Revision No. 105-29042-00030.
**The 100,000 CO_2e threshold represents the Title V and PSD subject to regulation thresholds for GHGs in order to determine whether a source's emissions are a regulated NSR pollutant under Title V and PSD. Prior to this permit revision, CO_2e emissions were not calculated because it was not a regulated pollutant at that time. GHGs as CO_2e emissions have been included with this permit revision (See the Proposed Changes section of this TSD).

(a) This existing source is not a major stationary source, under PSD (326 IAC 2-2), because no attainment regulated pollutant is emitted at a rate of 250 tons per year or more, and it is not one of the twenty-eight (28) listed source categories, as specified in 326 IAC 2-2-1(ff)(1).

(b) This existing source is not a major source of HAPs, as defined in 40 CFR 63.41, because the Permittee has accepted limits on HAPs emissions to less than ten (10) tons per year for any single HAP and less than twenty-five (25) tons per year of a combination of HAPs. Therefore, this source is an area source under Section 112 of the Clean Air Act (CAA).

Description of Proposed Revision

The Office of Air Quality (OAQ) has reviewed an application, submitted by Cook Incorporated on June 27, 2012, relating to the construction and operation of two (2) new sterilization chambers. The source currently has seven (7) permitted sterilization chambers at this facility.

The following is a list of the new emission unit(s) and pollution control device(s):

(a) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to Stacks CEV01 and CEV02, respectively, using no control;

Under 40 CFR 63, Subpart O, these emission units are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

Note 1: Each sterilization chamber is evacuated by a dedicated vacuum pump. The vacuum pumps deliver all evacuated gases to a sterilizer wet acid scrubber for treatment before discharge to the atmosphere. All seven (7) existing sterilization chambers and the two (2) new sterilization chambers (S1 through S9) are controlled by the one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01. Testing will be required for the primary wet acid scrubber with this significant permit revision.

Note 2: The new two (2) sterilization chambers will use the existing fourteen (14) aeration chambers (currently permitted and in use for the existing seven (7) sterilization chambers), where palletized product is degassed after removal from the sterilizers. Testing will be required for fourteen (14) aeration chambers with this significant permit revision.

Note 3: With this proposed revision, the source is not required to control emissions from the sterilization chamber exhaust vents (back vents) for S8 and S9, pursuant to 40 CFR 63, Subpart O (NESHAP for Ethylene Oxide Emissions Standards for Sterilization Facilities). The existing units, S1 through S7, are required to control emissions from the sterilization chamber exhaust vents (back vents) using a single nonregenerable dry bed reactor, pursuant to the source's 8-1-6 BACT for these facilities. The chamber exhaust vents (back vents) exhaust residual ethylene oxide when the sterilizer door is opened to remove the product.

Note 4: The size and production rate of the two (2) new ethylene oxide sterilization chambers is approved as confidential information, and has been submitted to IDEM, OAQ with this Significant Permit Revision application on June 27, 2012.

Insignificant Activities

The source has also indicated the following changes should be made to the list of insignificant activities:

(b) The following storage containers:

(1) ~~six (6)~~ **nine (9)** 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (2,400 pounds total). These are portable cylinders that will be connected to the sterilization process;

(2) ~~six (6)~~ **nine (9)** 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide on standby for connection to the sterilization process as cylinders are emptied;

...

(e) Natural gas fired combustion sources with a total heat input of ~~11.3~~ **20.45** MMBtu per hour~~;~~**, including the following:**

(1) One natural gas-fired boiler, identified as C238-F, constructed in 2000, with a maximum heat input capacity of 0.45 MMBtu per hour;

(2) One natural gas-fired boiler, identified as C240-F, constructed in 2003, with a maximum heat input capacity of 1.26 MMBtu per hour;

(3) One natural gas-fired boiler, identified as C241-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(4) One natural gas-fired boiler, identified as C242-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(5) One natural gas-fired boiler, identified as C239-F, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu per hour;

(6) One natural gas-fired boiler, identified as C246-F, constructed in 2004, with a maximum heat input capacity of 1.5 MMBtu per hour;

(7) One natural gas-fired boiler, identified as C230-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(8) One natural gas-fired boiler, identified as C231-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(9) One natural gas-fired boiler, identified as C232-F, constructed in 2006, with a maximum heat input capacity of 7.0 MMBtu per hour;

(10) One natural gas-fired boiler, identified as C233-F, constructed in 2006, with a maximum heat input capacity of 0.85 MMBtu per hour;

(11) One natural gas-fired boiler, identified as C364-F, constructed in 2010, with a maximum heat input capacity of 0.5 MMBtu per hour;

...

Enforcement Issues

There are no pending enforcement actions related to this revision.

Emission Calculations

See Appendix A of this TSD for detailed emission calculations.

Permit Level Determination – FESOP Revision

The following table is used to determine the appropriate permit level under 326 IAC 2-8.11.1. This table reflects the PTE before controls of the proposed revision. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Process/ Emission Unit	PTE of Proposed Revision (tons/year)									
	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	GHGs as CO_2e	Total HAPs	Worst Single HAP
Two (2) New Sterilization Chambers	-	-	-	-	-	24.04	-	-	24.04	24.04 (Ethylene Oxide)
Boilers	0.1	0.3	0.3	0.0	3.9	0.2	3.3	4,744	negl.	negl.
Total PTE of Proposed Revision	**0.1**	**0.3**	**0.3**	**0.0**	**3.9**	**24.24**	**3.3**	**4,744**	**24.04**	**24.04 (Ethylene Oxide)**

negl. = negligible

Note 1: The potential to emit (PTE) of the two (2) new sterilization chambers includes emissions from the entire sterilization process: (a) emissions from each sterilization chamber vacuum vent for units S8 and S9, which are controlled by the primary wet acid scrubber, (b) emissions from each chamber exhaust vent (back vent), (c) emissions from product transfer, and (d) emissions from aeration, using the existing fourteen (14) aerations rooms. See Appendix A for detailed calculations.

Note 2: The natural gas combustion units, under Insignificant Activities, are each less than 10 MMBtu per hour. Prior to this revision the total heat input capacity of all natural gas combustion units was 11.3 MMBtu per hour. With this revision, the heat input capacity is increasing from 11.3 MMBtu per hour to 20.45 MMBtu per hour. The PTE of Proposed Revision is calculated for the difference in heat input capacity (20.45 - 11.3 = 9.15 MMBtu per hour).

This FESOP is being revised through a FESOP Significant Permit Revision pursuant to 326 IAC 2-8-11.1(f)(1)(G) because it involves a modification with a potential to emit greater than or equal to ten (10) tons per year of a single HAP as defined under Section 112(b) of the CAA.

PTE of the Entire Source After Issuance of the FESOP Revision

The table below summarizes the potential to emit of the entire source, with updated emissions shown as **bold** values and previous emissions shown as ~~strikethrough~~ values. Note that emissions calculations for the Boiler and Emergency Generator have been updated and corrected as necessary.

Process/ Emission Unit	Potential To Emit of the Entire Source to accommodate the Proposed Revision (tons/year)									
	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	GHGs as CO_2e**	Total HAPs	Worst Single HAP
Sterilization **Process**	-	-	-	-	-	~~0.38~~ **9.4**	-	-	~~0.38~~ **9.4**	~~0.38~~ **9.4** (ethylene oxide)
Surface Coating	-	-	-	-	-	2.05	-	-	0.01	0.01 (methanol)
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	-	0.12	0.12 (methanol)
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-	-
Boiler**s**	~~0.09~~ **0.17**	~~0.38~~ **0.67**	~~0.38~~ **0.67**	~~0.03~~ **0.05**	~~4.97~~ **8.78**	~~0.27~~ **0.48**	~~4.17~~ **7.38**	**10,602**	~~0.09~~ **0.17**	~~0.09~~ **0.16** (hexane)
Emergency **Diesel** Generators ~~(Unit #1 and Unit #2): Diesel Combustion~~	0.84	~~0.84~~ **0.48**	~~0.84~~ **0.48**	4.83	28.63	~~0.32~~ **0.84**	**6.56**	**1,389**	~~1.25 E-02~~ **0.01**	6.48E-03 (benzene)
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	-	0.17	0.09 (TCE)
Total PTE of Entire Source	~~1.07~~ **1.14**	~~1.35~~ **1.29**	~~1.35~~ **1.29**	~~4.86~~ **4.88**	~~33.60~~ **37.41**	~~18.99~~ **28.22**	~~10.74~~ **13.94**	**11,991**	~~0.79~~ **9.88**	~~0.38~~ **9.40** (ethylene oxide)
Title V Major Source Thresholds**	NA	100	100	100	100	100	100	100,000	25	10
PSD Major Source Thresholds**	250	250	250	250	250	250	250	100,000	NA	NA

negl. = negligible
**The 100,000 CO_2e threshold represents the Title V and PSD subject to regulation thresholds for GHGs in order to determine whether a source's emissions are a regulated NSR pollutant under Title V and PSD.

Note 1: The potential to emit (PTE) after issuance of the FESOP for the sterilization process takes into account the FESOP limit on HAPs (ethylene oxide). The table in Technical Support Document (TSD) to Significant Permit Revision No. 105-29042-00030 listed the controlled PTE for the sterilization process, not the limited PTE.

Note 2: The potential to emit (PTE) of the sterilization process include: (a) emissions from each sterilization chamber vacuum vent (S1 through S9), which are each controlled by the primary wet acid scrubber, (b) emissions from each chamber exhaust vent (back vent), which are controlled for units S1 through S7 and uncontrolled for units S8 and S9, (c) emissions from product transfer, and (d) emissions from aeration, using fourteen (14) aerations rooms. See Appendix A for detailed calculations.

The table below summarizes the potential to emit of the entire source after issuance of this revision, reflecting all limits, of the emission units. Any control equipment is considered federally enforceable only after issuance of this FESOP permit revision, and only to the extent that the effect of the control equipment is made practically enforceable in the permit. Note: the table below was generated from the above table, with bold text un-bolded and strikethrough text deleted.

Process/ Emission Unit	Potential To Emit of the Entire Source to accommodate the Proposed Revision (tons/year)									
	PM	PM10	PM2.5	SO_2	NOx	VOC	CO	GHGs as CO_2e**	Total HAPs	Worst Single HAP
Sterilization Process	-	-	-	-	-	9.4	-	-	9.4	9.4 (ethylene oxide)
Surface Coating	-	-	-	-	-	2.05	-	-	0.01	0.01 (methanol)
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	-	0.12	0.12 (methanol)
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-	-
Boilers	0.17	0.67	0.67	0.05	8.78	0.48	7.38	10,602	0.17	0.16 (hexane)
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	1,389	0.01	6.48E-03 (benzene)
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	-	0.17	0.09 (TCE)
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**28.22**	**13.94**	**11,991**	**9.88**	**9.40 (ethylene oxide)**
Title V Major Source Thresholds**	NA	100	100	100	100	100	100	100,000	25	10
PSD Major Source Thresholds**	250	250	250	250	250	250	250	100,000	NA	NA

negl. = negligible
**The 100,000 CO_2e threshold represents the Title V and PSD subject to regulation thresholds for GHGs in order to determine whether a source's emissions are a regulated NSR pollutant under Title V and PSD.

(a) FESOP Status

This revision to an existing Title V minor stationary source will not change the minor status, because the potential to emit criteria pollutants from the entire source will still be limited to less than the Title V major source threshold levels. Therefore, the source will still be subject to the provisions of 326 IAC 2-8 (FESOP).

In order to comply with the requirements of 326 IAC 2-8-4 (FESOP), the source shall comply with the following:

(1) The total ethylene oxide emissions from the nine (9) ethylene oxide sterilization chambers and the fourteen (14) aeration rooms shall be less than 9.40 tons per twelve (12) consecutive month period, total, with compliance determined at the end of each month

Note: This is an existing requirement; except the limit now includes the additional two (2) new

sterilization chambers to the seven (7) existing sterilization chambers.

Compliance with these limits, combined with the potential to emit HAPs from all other emission units at this source, shall limit the source-wide total potential to emit of any single HAP to less than ten (10) tons per 12 consecutive month period, total HAPs to less than twenty-five (25) tons per 12 consecutive month period, and shall render 326 IAC 2-7 (Part 70 Permits) and 326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP) not applicable.

(b) PSD Minor Source
This modification to an existing PSD minor stationary source will not change the PSD minor status, because the potential to emit of all attainment regulated pollutants from the entire source will continue to be less than the PSD major source threshold levels. Therefore, pursuant to 326 IAC 2-2, the PSD requirements do not apply.

Federal Rule Applicability Determination

New Source Performance Standards (NSPS)

(a) Each of the natural gas fired boilers, constructed after June 9, 1989, has a heat input capacity of less than 10 MMBtu per hour, and pursuant to 40 CFR 60.40c(a) these units are not subject to the requirements of 40 CFR 60, Subpart Dc - Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units.

(b) There are no New Source Performance Standards (NSPS) (326 IAC 12 and 40 CFR Part 60) included for this proposed revision.

National Emission Standards for Hazardous Air Pollutants (NESHAP)

(c) The two (2) new ethylene oxide sterilizatio chambers are subject to the National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Emissions Standards for Sterilization Facilities (40 CFR 63, Subpart O), because this source is a sterilization facility using ten (1) tons or more of ethylene oxide per twelve (12) consecutive month period.

Note: The provisions of NESHAP Subpart O are already included in the permit.

Applicable portions of the NESHAP are the following:
(1) 40 CFR 63.360,
(2) 40 CFR 63.361,
(3) 40 CFR 63.362,
(4) 40 CFR 63.363(a), (b)(1), (b)(2), (c), (e), (f),
(5) 40 CFR 63.364(a), (b), (d), (e),
(6) 40 CFR 63.365,
(7) 40 CFR 63.366,
(8) 40 CFR 63.367,
(9) 40 CFR 63.368.

The requirements of 40 CFR Part 63, Subpart A – General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the source except as otherwise specified in 40 CFR 63, Subpart O.

Note: See Compliance Determination, Monitoring and Testing Requirements section below for testing requirements related to this NESHAP.

(d) The requirements of the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Hospital Ethylene Oxide Sterilizers, 40 CFR 63, Subpart WWWWW (5W), are not included for this proposed revision, since this source is not a hospital.

(e) There are no other National Emission Standards for Hazardous Air Pollutants (NESHAPs) (326 IAC 14, 326 IAC 20 and 40 CFR Part 63) included for this proposed revision.

Compliance Assurance Monitoring (CAM)

(f) Pursuant to 40 CFR 64.2, Compliance Assurance Monitoring (CAM) is not included in the permit, because the potential to emit of the source is limited to less than the Title V major source thresholds and the source is not required to obtain a Part 70 or Part 71 permit.

State Rule Applicability Determination

The following state rules are applicable to the proposed revision:

(a) 326 IAC 2-8-4 (FESOP)
This revision to an existing Title V minor stationary source will not change the minor status, because the potential to emit criteria pollutants from the entire source will still be limited to less than the Title V major source threshold levels. Therefore, the source will still be subject to the provisions of 326 IAC 2-8 (FESOP). See PTE of the Entire Source After Issuance of the FESOP Revision Section above.

(b) 326 IAC 2-2 (Prevention of Significant Deterioration(PSD))
This modification to an existing PSD minor stationary source will not change the PSD minor status, because the potential to emit of all attainment regulated pollutants from the entire source will continue to be less than the PSD major source threshold levels. Therefore, pursuant to 326 IAC 2-2, the PSD requirements do not apply. See PTE of the Entire Source After Issuance of the FESOP Revision Section above.

(c) 326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP))
The unlimited potential to emit of HAPs from the two (2) new sterilization chambers is greater than ten (10) tons per year for any single HAP and/or greater than twenty-five (25) tons per year of a combination of HAPs. However, the source shall limit the potential to emit of HAPs from the all nine (9) sterilization chambers to less than ten (10) tons per year for any single HAP and less than twenty-five (25) tons per year of a combination of HAPs. Therefore, the proposed revision is not subject to the requirements of 326 IAC 2-4.1. See PTE of the Entire Source After Issuance of the FESOP Revision Section above.

(d) 326 IAC 2-6 (Emission Reporting)
Pursuant to 326 IAC 2-6-1, this source is not subject to this rule, because it is not required to have an operating permit under 326 IAC 2-7 (Part 70), it is not located in Lake, Porter, or LaPorte County, and it does not emit lead into the ambient air at levels equal to or greater than 5 tons per year. Therefore, 326 IAC 2-6 does not apply.

(e) 326 IAC 5-1 (Opacity Limitations)
Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(1) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(2) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

(f) 326 IAC 6-4 (Fugitive Dust Emissions Limitations)

Pursuant to 326 IAC 6-4 (Fugitive Dust Emissions Limitations), the source shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4.

Ethylene Oxide Sterilization Chambers

(g) 326 IAC 8-1-6 (New Facilities, General Reduction Requirements)
Each new sterilization chamber is not subject to the requirements of 326 IAC 8-1-6, since the unlimited VOC potential emissions from each new sterilization chamber is less than twenty-five (25) tons per year.

Note: The existing sterilization chambers are subject to the requirements of 326 IAC 8-1-6.

(h) There are no 326 IAC 8 (VOC) rules applicable to the sterilization chambers.

(i) 326 IAC 12 (New Source Performance Standards)
See Federal Rule Applicability Section of this TSD.

(j) 326 IAC 20 (Hazardous Air Pollutants)
See Federal Rule Applicability Section of this TSD.

Natural Gas-Fired Boilers

(k) 326 IAC 6-2 (Particulate Emission Limitations for Sources of Indirect Heating)
Each of the natural gas-fired boilers are constructed after September 21, 1983; pursuant to 326 IAC 6-2-1(d), each of these units is subject to the requirements of this rule.

Pursuant to 326 IAC 6-2-4, particulate emissions from each individual boiler shall be limited as follows:

Year Constructed	Unit ID	Heat input capacity added with year constructed (MMBtu/hr)	Q (total source capacity) (MMBtu/hr)	**6-2-4 Emission Limit Pt (lb PM /MMBtu)**	Potential to emit PM of existing units by year (lbs/hour)	Calculated Pt for each individual unit (lb PM /MMBtu)
2000	C238-F	0.45	0.45	**0.6**	0.0008	0.0019
2003	C240-F C241-F C242-F	1.26 + 2.1349 + 2.1349 = 5.53	= 0.45 + 5.53 = 5.98	**0.6**	0.011	0.0019
2004	C239-F C246-F	1.26 + 1.5 = 2.76	= 5.98 + 2.76 = 8.74	**0.6**	0.016	0.0019
2006	C230-F C231-F C232-F C233-F	= 1.68 + 1.68 + 7.0 + 0.85 = 11.21	= 8.74 + 11.21 =19.95	**0.5**	0.037	0.0019
2010	C364-F	0.5	= 19.95 + 0.5 = 20.45	**0.5**	0.038	0.0019

Particulate emissions from indirect heating facilities constructed after September 21, 1983 shall be limited by the following equation:

$$Pt = \frac{1.09}{Q^{0.26}}$$

Pt = pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input.
Q = Total source maximum operating capacity in MMBtu/hr heat input. Maximum operating capacity is defined as the maximum capacity at which the unit is operated or the nameplate capacity, whichever is specified in the permit application, except when a lower limitation is contained in the facility's operating permit.

For Q less than 10 mmBtu/hr, Pt shall not exceed 0.6. For Q greater than or equal to 10,000 mmBtu/hr, Pt shall not exceed 0.1.

Potential to emit PM of existing units by year (lbs/hour)
= Potential to emit (tons/year) * 2000 (lbs/ton) / 8760 (hrs/yr)

Calculated Pt for each individual unit (lb PM /MMBtu)
= Potential to emit PM (lb/hr) / Total source capacity (MMBtu/hr)

Note: This is a new requirement with this permit revision.

Compliance Determination, Monitoring and Testing Requirements

(a) The existing compliance determination and monitoring requirements will not change as a result of this revision. The source shall continue to comply with the applicable requirements and permit conditions as contained in FESOP No: 105-29042-00030, issued on June 25, 2010.

(b) The testing requirements applicable to this proposed revision are as follows:

Testing Requirements				
Emission Units / Process	**Control Device(s)**	**Pollutant**	**Timeframe for Testing**	**Frequency of Testing**
Sterilization	primary wet acid scrubber (exhausting to stack PS01)(1)	Ethylene Oxide	Not later than 180 days after initial start up of the 2 new sterilization chambers S8 & S9	Repeat every five (5) years
Fourteen (14) aeration rooms	one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel) (exhausting to stack HV01)(2)	Ethylene Oxide	Not later than 180 days after initial start up of the 2 new sterilization chambers S8 & S9	Repeat every five (5) years

Notes:
(1) This testing is required to ensure the primary wet acid scrubber will control emissions with at least 99% efficiency, and to ensure compliance with 326 IAC 8-1-6 (BACT) and 40 CFR Subpart O and in order to confirm the FESOP (326 IAC 2-8) status of the source.
(2) The existing fourteen (14) aerations rooms will be utilized for the existing sterilization process and with the additional two (2) new sterilization chambers, S8 and S9, included with this permit revision. The controls for the aeration rooms are required to have an efficiency of at least 99%. Testing is required to ensure compliance with 326 IAC 8-1-6 (BACT) and 40 CFR Subpart O and in order to confirm the FESOP (326 IAC 2-8) status of the source.

Testing shall be repeated at least once every five (5) years the date of the most recent valid compliance demonstration in order to demonstrate compliance with the source's FESOP.

The existing sterilization chamber exhaust vents (back vents) for units S1 through S7, controlled by one (1) single non-regenerable dry bed reactor, have existing monitoring and record keeping requirements sufficient to determine compliance; further, the back vents have minimal ethylene oxide emissions. The back vents for S8 & S9 are uncontrolled. The source was required to

perform an initial performance test for these emission units with its original FESOP. Therefore, repeat testing will not be required for the sterilization chamber exhaust vents (back vents).

Proposed Changes

(a) The following changes listed below are due to the proposed revision:

(1) Section A.2, A.3, and D.1 have been updated to include the equipment changes.

(2) The address throughout the permit documents has been updated to the correct address as "6330." Previously, both "6300" and "6330" have been used by the source as the source location; from this point forward, though, the source address will be identified solely as "6330."

(3) Section D.1.2 has been updated to include the two (2) new sterilization chambers in the existing HAP emission limitation.

(4) A testing requirement has been added as Condition D.1.5, and all subsequent Conditions in Section D.1 have been renumbered.

(5) Section D.3 has been added to incorporate the requirements for the natural gas-fired boilers.

(6) Section E.1 has been update to include the two (2) new sterilization chambers.

Deleted language appears as ~~strikethrough~~ text and new language appears as **bold** text:

...

Source Address: ~~6300~~ **6330** North Matthews Drive, Ellettsville, Indiana 47429

...

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-8-3(c)(3)]

This stationary source consists of the following emission units and pollution control devices:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and **with chamber exhaust vents (back vents) exhausting to** one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 ~~will be~~ **was** constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to Stacks CEV01 and CEV02, respectively, using no control;

~~(b)~~**(c)** Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely

through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

Under 40 CFR 63, Subpart O, emission units (a)**,** ~~and~~ (b)**, and (c)** listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

~~(c)~~**(d)** Miscellaneous cleaning with isopropyl alcohol (IPA).

~~(d)~~**(e)** One (1) diesel-fired emergency generator, identified as Unit #1, installed on July 31, 2003 and approved for construction in 2010, with a maximum capacity of 1850 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

~~(e)~~**(f)** One (1) diesel-fired emergency generator, identified as Unit #2, installed on November 19, 2003 and approved for construction in 2010, with a maximum capacity of 2922 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

...

A.3 Insignificant Activities [326 IAC 2-7-1(21)][326 IAC 2-8-3(c)(3)(I)]

This stationary source also includes the following insignificant activities:

...

(b) The following storage containers:

(1) ~~six (6)~~ **nine (9)** 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (2,400 pounds total). These are portable cylinders that will be connected to the sterilization process;

(2) ~~six (6)~~ **nine (9)** 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide on standby for connection to the sterilization process as cylinders are emptied;

...

(e) Natural gas fired combustion sources with a total heat input of ~~11.3~~ **20.45** MMBtu per hour~~;~~**, including the following:**

(1) One natural gas-fired boiler, identified as C238-F, constructed in 2000, with a maximum heat input capacity of 0.45 MMBtu per hour;

(2) One natural gas-fired boiler, identified as C240-F, constructed in 2003, with a maximum heat input capacity of 1.26 MMBtu per hour;

(3) One natural gas-fired boiler, identified as C241-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(4) One natural gas-fired boiler, identified as C242-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(5) One natural gas-fired boiler, identified as C239-F, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu per hour;

(6) One natural gas-fired boiler, identified as C246-F, constructed in 2004, with a maximum heat input capacity of 1.5 MMBtu per hour;

(7) One natural gas-fired boiler, identified as C230-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(8) One natural gas-fired boiler, identified as C231-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(9) One natural gas-fired boiler, identified as C232-F, constructed in 2006, with a maximum heat input capacity of 7.0 MMBtu per hour;

(10) One natural gas-fired boiler, identified as C233-F, constructed in 2006, with a maximum heat input capacity of 0.85 MMBtu per hour;

(11) One natural gas-fired boiler, identified as C364-F, constructed in 2010, with a maximum heat input capacity of 0.5 MMBtu per hour;

...

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and **with chamber exhaust vents (back vents) exhausting to** one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to Stacks CEV01 and CEV02, respectively, using no control;

~~(b)~~**(c)** Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

~~(c) Miscellaneous cleaning with isopropyl alcohol (IPA).~~

Under 40 CFR 63, Subpart O, emission units (a)**,** ~~through~~ (b)**, and (c)** listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

D.1.1 Ethylene Oxide [326 IAC 8-1-6]

Pursuant to FESOP F105-8436-00030, issued on February 16, 1998, **and 326 IAC 8-1-6,** the following control technology will also serve as the Best Available Control Technology (BACT) for the sterilization operation**s S1 through S7**. The control technology used to comply with the requirements of 40 CFR ~~60.360 through 60.367~~ **63.360 through 63.367**, which apply to the sterilization process, in addition to the following:

(a) A single nonregenerable dry bed reactor to reduce ethylene oxide emissions to a

maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, to control the seven (7) sterilization chamber exhaust vents~~.~~**, identified as units S1 through S7**.

(b) A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) with a control efficiency of 99% to control emissions from the fourteen (14) aeration rooms.

The requirements listed above will control ~~VOC (~~ethylene oxide~~)~~ emissions from the sterilization operation**s S1 through S7 such that ethylene oxide emissions from S1 through S7 shall not exceed** ~~to~~ 0.38 tons per year.

Since the requirement to operate the dry bed reactor controlling the emissions from the sterilization chamber exhaust vents **(back vents)** in the original FESOP was also part of the requirements to satisfy 326 IAC 8-1-6 (New Facilities, General Reduction Requirements), the source is still required to operate the dry bed reactor controlling emissions from the sterilization chamber exhaust vents **(back vents) for units S1 through S7 in order to comply with 326 IAC 8-1-6, even though a control for emissions from back vents is not required by NESHAP Subpart O [40 CFR 63.36]; the source is also required to operate** ~~as well as~~ the primary wet acid scrubber **to control emissions from the sterilization chambers**, **as well as** the wet acid pre-scrubber~~,~~ and three (3) dry bed reactors (in parallel) **to control emissions from the fourteen (14) aerations rooms in order** to comply with 326 IAC 8-1-6 (New Facilities, General Reduction Requirements).

Note: The source will not be required to operate the dry bed reactor to control emissions from the sterilization chamber exhaust vents (back vents) from the two (2) sterilizers S8 and S9, approved for construction in 2012. S8 and S9 are not subject to the requirements of 326 IAC 8-1-6.

D.1.2 Hazardous Air Pollutants (HAPs) [326 IAC 2-8-4]

Pursuant to 326 IAC 2-8, the total ethylene oxide emissions from the ~~seven (7)~~ **nine (9)** ethylene oxide sterilization chambers and the fourteen (14) aeration rooms shall be less than 9.40 tons per twelve (12) consecutive month period, total, with compliance determined at the end of each month

Compliance with the above limit, combined with the potential to emit ethylene oxide from other emission units at the source, shall limit the ethylene oxide from the entire source to less than 10 tons per twelve (12) consecutive month period**, total HAPs to less than twenty-five (25) tons per 12 consecutive month period,** and render 326 IAC 2-7 (Part 70 Permits) **and 326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP)** not applicable.

...

Compliance Determination Requirements [326 IAC 2-8-4] [326 IAC 2-8-5(a)(1)]

D.1.4 Ethylene Oxide Control [326 IAC 8-1-6] [326 IAC 2-8-4]

(a) In order to comply with Conditions D.1.1, and D.1.2, the primary wet acid scrubber and the single non-regenerable dry bed reactor shall be in operation and control emissions from the seven (7) ethylene oxide sterilization chambers **S1 through S7** at all times the ~~seven (7)~~ ethylene oxide sterilization chambers are in operation.

(b) In order to comply with Conditions D.1.1, and D.1.2, the primary wet acid scrubber shall be in operation and control emissions from the two (2) ethylene oxide sterilization chambers S8 and S9 at all times the ethylene oxide sterilization chambers are in operation.

~~(b)~~**(c)** In order to comply with Conditions D.1.1, and D.1.2, the three (3) dry bed reactors with or without the wet acid pre-scrubber shall be in operation and control emissions from the fourteen (14) aeration rooms at all times the fourteen (14) aeration rooms are in operation.

D.1.5 Testing Requirements [326 IAC 2-8-5(a)(1)] [326 IAC 2-1.1-11] [40 CFR Part 63, Subpart O]

In order to demonstrate the compliance status with Condition D.1.1, Condition D.1.2, and Condition E.1.2, not later than 180 days after the startup of sterilization chambers S8 and S9, the Permittee shall perform a performance test on each of the following control devices:

(a) The one (1) primary wet acid scrubber, exhausting to stack PS01, controlling ethylene oxide emissions from the nine (9) sterilization chamber S1 through S9;

(b) The one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), exhausting to stack HV01, controlling ethylene oxide emissions from the fourteen (14) aeration rooms;

using the procedures listed in 40 CFR 63.7 of Subpart A, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. During the performance test, the owner or operator shall determine the efficiency of the control devices and the site-specific operating parameters for each of the wet acid scrubbers and the dry bed reactors. This test shall be repeated at least once every five (5) years the date of the most recent valid compliance demonstration. Testing shall be conducted in accordance with the provisions of 326 IAC 3-6 (Source Sampling Procedures). Section C - Performance Testing contains the Permittee's obligation with regard to the performance testing required by this condition.

Compliance Monitoring Requirements [326 IAC 2-8-4] [326 IAC 2-8-5(a)(1)]

D.1.~~5~~**6** Monitoring

To demonstrate the compliance status with the control efficiency and emission limitations requirements in conditions D.1.1, and D.1.2:

(a) for the single non-regenerable dry bed reactor controlling ethylene oxide emissions from the seven (7) sterilization chamber exhaust vents **(back vents) for units S1 through S7**, the Permittee shall monitor and record the number of equivalent sterilization cycles performed while the bed is in service.

(b) The Permittee shall keep a record of the number of sterilization cycles run for ~~each~~ sterilizer **units S1 through S7**, convert this to equivalent cycles for a 512 ft^3 sterilizer, and keep a daily running record of total equivalent cycles. Upon reaching 2,917 equivalent sterilization cycles, based on the manufacturer's guaranteed bed capacity of 360 pounds of ethylene oxide, the performance of the dry bed reactor is assumed to drop below 99% removal efficiency and the bed material will have to be removed and replaced with fresh reactant.

D.1.~~6~~**7** Record Keeping Requirements

(a) To document the compliance status with Conditions D.1.1, D.1.2, and D.1.~~5~~**6**, the Permittee shall maintain records in accordance with (1) and (2) below. Records maintained for (1) shall be taken daily and shall be complete and sufficient to establish compliance with the ethylene oxide emission limits and/or control efficiency limits established in Conditions D.1.1, and D.1.2, and the monitoring requirements established in Condition D.1.~~5~~**6**. Records maintained for (2) shall be taken daily and shall be used for reference purposes only. Records necessary to demonstrate compliance shall be available within 30 days of the end of each compliance period.

...

SECTION D.3 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(e) Natural gas fired combustion sources with a total heat input of 20.45 MMBtu per hour, including the following:

(1) One natural gas-fired boiler, identified as C238-F, constructed in 2000, with a maximum heat input capacity of 0.45 MMBtu per hour;

(2) One natural gas-fired boiler, identified as C240-F, constructed in 2003, with a maximum heat input capacity of 1.26 MMBtu per hour;

(3) One natural gas-fired boiler, identified as C241-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(4) One natural gas-fired boiler, identified as C242-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(5) One natural gas-fired boiler, identified as C239-F, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu per hour;

(6) One natural gas-fired boiler, identified as C246-F, constructed in 2004, with a maximum heat input capacity of 1.5 MMBtu per hour;

(7) One natural gas-fired boiler, identified as C230-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(8) One natural gas-fired boiler, identified as C231-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(9) One natural gas-fired boiler, identified as C232-F, constructed in 2006, with a maximum heat input capacity of 7.0 MMBtu per hour;

(10) One natural gas-fired boiler, identified as C233-F, constructed in 2006, with a maximum heat input capacity of 0.85 MMBtu per hour;

(11) One natural gas-fired boiler, identified as C364-F, constructed in 2010, with a maximum heat input capacity of 0.5 MMBtu per hour;

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.3.1 Particulate Matter [326 IAC 6-2]

Pursuant to 326 IAC 6-2-4, particulate emissions from each individual boiler shall be limited as follows:

Unit ID	PM Emission Limit (lb/MMBtu)
C238-F	0.6
C240-F	0.6
C241-F	0.6

C242-F	**0.6**
C239-F	**0.6**
C246-F	**0.6**
C230-F	**0.5**
C231-F	**0.5**
C232-F	**0.5**
C233-F	**0.5**
C364-F	**0.5**

Particulate emissions from indirect heating facilities constructed after September 21, 1983 shall be limited by the following equation:

$$Pt = \frac{1.09}{Q^{0.26}}$$

Pt = pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input.
Q = Total source maximum operating capacity in MMBtu/hr heat input. Maximum operating capacity is defined as the maximum capacity at which the unit is operated or the nameplate capacity, whichever is specified in the permit application, except when a lower limitation is contained in the facility's operating permit.

...

SECTION E.1 SOURCE OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and **with chamber exhaust vents (back vents) exhausting to** one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to Stacks CEV01 and CEV02, respectively, using no control;

~~(b)~~**(c)** Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

~~(c) Miscellaneous cleaning with isopropyl alcohol (IPA).~~

Under 40 CFR 63, Subpart O, emission units (a)**,** ~~through~~ (b)**, and (c)** listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

...

SECTION E.2 EMISSIONS UNIT OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

~~(d)~~**(e)** One (1) diesel-fired emergency generator, identified as Unit #1, installed on July 31, 2003 and approved for construction in 2010, with a maximum capacity of 1850 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

~~(e)~~**(f)** One (1) diesel-fired emergency generator, identified as Unit #2, installed on November 19, 2003 and approved for construction in 2010, with a maximum capacity of 2922 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

...

(b) Upon further review, IDEM, OAQ has decided to make the following changes to the permit. Deleted language appears as ~~strikethrough~~ text and new language appears as **bold** text:

(1) Pursuant to 326 IAC 2-7-1(39), starting July 1, 2011, greenhouse gases (GHGs) emissions are subject to regulation at a source with a potential to emit (PTE) 100,000 tons per year or more of CO2 equivalent emissions (CO2e). Therefore, CO2e emissions have been calculated for this source. Based on the calculations, the unlimited PTE GHGs from the entire source is less than 100,000 tons of CO2e per year (see TSD Appendix A for detailed calculations). Section C.2 - Overall Source Limit has been updated as follows:

C.2 Overall Source Limit [326 IAC 2-8]

The purpose of this permit is to limit this source's potential to emit to less than major source levels for the purpose of Section 502(a) of the Clean Air Act.

(a) Pursuant to 326 IAC 2-8:

(1) The potential to emit any regulated pollutant, except particulate matter (PM) **and greenhouse gases (GHGs)**, from the entire source shall be limited to less than one hundred (100) tons per twelve (12) consecutive month period.

(2) The potential to emit any individual hazardous air pollutant (HAP) from the entire source shall be limited to less than ten (10) tons per twelve (12) consecutive month period; and

(3) The potential to emit any combination of HAPs from the entire source shall be limited to less than twenty-five (25) tons per twelve (12) consecutive month period.

(4) The potential to emit greenhouse gases (GHGs) from the entire source shall be limited to less than one hundred thousand (100,000) tons of CO2 equivalent emissions (CO2e) per twelve (12) consecutive month period.

...

(2) On October 27, 2010, the Indiana Air Pollution Control Board issued revisions to 326 IAC 2. These revisions resulted in changes to the rule sites listed in the permit. These

changes are not changes to the underlining provisions. The change is only to site of these rules in Section B - Operational Flexibility. IDEM, OAQ has clarified the rule sites for the Preventive Maintenance Plan.

B.11 Preventative Maintenance Plan [326 IAC 1-6-3][326 IAC 2-8-4(9)]~~[326 IAC 2-8-5(a)(1)]~~

...

B.18 Operational Flexibility [326 IAC 2-8-15][326 IAC 2-8-11.1]

(a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-8-15(b) **and (c)** ~~through (d)~~ without a prior permit revision, if each of the following conditions is met:

(1) The changes are not modifications under any provision of Title I of the Clean Air Act;

(2) Any approval required by 326 IAC 2-8-11.1 has been obtained;

(3) The changes do not result in emissions which exceed the limitations provided in this permit (whether expressed herein as a rate of emissions or in terms of total emissions);

(4) The Permittee notifies the:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Regulation Development Branch - Indiana (AR-18J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

in advance of the change by written notification at least ten (10) days in advance of the proposed change. The Permittee shall attach every such notice to the Permittee's copy of this permit; and

(5) The Permittee maintains records on-site, on a rolling five (5) year basis, which document all such changes and emission trades that are subject to 326 IAC 2-8-15~~(b)(2), (c)(1), and (d)~~ **(b)(1) and (c)**. The Permittee shall make such records available, upon reasonable request, for public review.

Such records shall consist of all information required to be submitted to IDEM, OAQ in the notices specified in 326 IAC 2-8-15~~(b)(2), (c)(1), and (d)~~ **(b)(1) and (c).**

(b) Emission Trades [326 IAC 2-8-15 ~~(c)~~ **(b)**]
The Permittee may trade emissions increases and decreases at the source, where the applicable SIP provides for such emission trades without requiring a permit revision, subject to the constraints of Section (a) of this condition and those in 326 IAC 2-8-15 ~~(c)~~ **(b)**.

(c) Alternative Operating Scenarios [326 IAC 2-8-15 ~~(d)~~ **(c)**]

The Permittee may make changes at the source within the range of alternative operating scenarios that are described in the terms and conditions of this permit in accordance with 326 IAC 2-8-4(7). No prior notification of IDEM, OAQ, or U.S. EPA is required.

(d) Backup fuel switches specifically addressed in, and limited under, Section D of this permit shall not be considered alternative operating scenarios. Therefore, the notification requirements of part (a) of this condition do not apply.

...

(3) IDEM, OAQ has clarified the Permittee's responsibility with regards to record keeping.

C.15 General Record Keeping Requirements [326 IAC 2-8-4(3)] [326 IAC 2-8-5]

(a) Records of all required monitoring data, reports and support information required by this permit shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. **Support information includes the following:**

(AA) All calibration and maintenance records.
(BB) All original strip chart recordings for continuous monitoring instrumentation.
(CC) Copies of all reports required by the FESOP.

Records of required monitoring information include the following:

(AA) The date, place, as defined in this permit, and time of sampling or measurements.
(BB) The dates analyses were performed.
(CC) The company or entity that performed the analyses.
(DD) The analytical techniques or methods used.
(EE) The results of such analyses.
(FF) The operating conditions as existing at the time of sampling or measurement.

These records shall be physically present or electronically accessible at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

...

(4) IDEM, OAQ has clarified the interaction of the Quarterly Deviation and Compliance Monitoring Report and the Emergency Provisions.

C.16 General Reporting Requirements [326 IAC 2-8-4(3)(C)] [326 IAC 2-1.1-11]

(a) The Permittee shall submit the attached Quarterly Deviation and Compliance Monitoring Report or its equivalent. **Proper notice submittal under Section B –Emergency Provisions satisfies the reporting requirements of this paragraph**. Any deviation from permit requirements, the date(s) of each deviation, the cause of the deviation, and the response steps taken must be reported except that a deviation required to be reported pursuant to an applicable requirement that exists independent of this permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. This report shall be submitted not later than thirty (30) days after the end of the reporting period. The Quarterly Deviation and Compliance Monitoring Report shall include a certification that meets the requirements of

326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1). A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit.

...

FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT

...

This report shall be submitted quarterly based on a calendar year. **Proper notice submittal under Section B –Emergency Provisions satisfies the reporting requirements of paragraph (a) of Section C-General Reporting.** Any deviation from the requirements of this permit, the date(s) of each deviation, the probable cause of the deviation, and the response steps taken must be reported. A deviation required to be reported pursuant to an applicable requirement that exists independent of the permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. Additional pages may be attached if necessary. If no deviations occurred, please specify in the box marked "No deviations occurred this reporting period".

...

Conclusion and Recommendation

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant. An application for the purposes of this review was received on June 27, 2012. Additional information was received on July 3, 2012 and July 31, 2012.

The construction and operation of this proposed revision shall be subject to the conditions of the attached proposed FESOP Significant Revision No. F105-32055-00030. The staff recommends to the Commissioner that this FESOP Significant Revision be approved.

IDEM Contact

(a) Questions regarding this proposed permit can be directed to Sarah Street at the Indiana Department Environmental Management, Office of Air Quality, Permits Branch, 100 North Senate Avenue, MC 61-53 IGCN 1003, Indianapolis, Indiana 46204-2251 or by telephone at (317) 2-8427 or toll free at 1-800-451-6027 extension 2-8427

(b) A copy of the findings is available on the Internet at: http://www.in.gov/ai/appfiles/idem-caats/

(c) For additional information about air permits and how the public and interested parties can participate, refer to the IDEM's Guide for Citizen Participation and Permit Guide on the Internet at: www.in.gov/idem

Appendix A: Emissions Calculations
Source-Wide Summary

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Significant Permit Revision No.: 105-32055-00030
Reviewer: Sarah Street

Uncontrolled Potential To Emit of the Entire Source (tons/year)										
Process / Emission Unit	**PM**	**PM10**	**PM2.5**	**SO_2**	**NOx**	**VOC**	**CO**	**GHGs as CO_2e**	**Total HAPs**	**Worst Single HAP**
Sterilization (S1 to S7)	-	-	-	-	-	37.80	-	-	37.80	37.80 Ethylene Oxide
Sterilization (S8 to S9)	-	-	-	-	-	24.04	-	-	24.04	24.04 Ethylene Oxide
Surface Coating	-	-	-	-	-	2.05	-	-	0.01	0.01 Methanol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	-	0.12	0.12 Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-	-
Boilers	0.17	0.67	0.67	0.05	8.78	0.48	7.38	10,602	0.17	0.16 Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	1,389	0.01	6.48E-03 Benzene
Insignificant Activities*	0.14	0.14	0.14	-	-	0.32	-	-	0.17	0.09 TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**80.66**	**13.94**	**11,991**	**62.32**	**61.84 Ethylene Oxide**

This Significant Permit Revision includes the addtion of two (2) new sterilization chambers, with PTE of 24.04 tons per year of VOC and Ethylene Oxide (ETO)
*Insignificant Activity Emissions represent emissions from various assembly operations including gluing, package prep and printing.

Limited Potential To Emit of the Entire Source (tons/year)										
Process / Emission Unit	**PM**	**PM10**	**PM2.5**	**SO_2**	**NOx**	**VOC**	**CO**	**GHGs as CO_2e**	**Total HAPs**	**Worst Single HAP**
Sterilization (S1 to S7)	-	-	-	-	-	9.40	-	-	9.40	9.40 Ethylene Oxide
Sterilization (S8 to S9)	-	-	-	-	-		-	-		
Surface Coating	-	-	-	-	-	2.05	-	-	0.01	0.01 Methanol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	-	0.12	0.12 Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-	-
Boilers	0.17	0.67	0.67	0.05	8.78	0.48	7.38	10,602	0.17	0.16 Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	1,389	0.01	6.48E-03 Benzene
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	-	0.17	0.09 TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**28.22**	**13.94**	**11,991**	**9.88**	**9.40 Ethylene Oxide**

Controlled Potential To Emit of the Entire Source (tons/year)										
Process / Emission Unit	**PM**	**PM10**	**PM2.5**	**SO_2**	**NOx**	**VOC**	**CO**	**GHGs as CO_2e**	**Total HAPs**	**Worst Single HAP**
Sterilization (S1 to S7)	-	-	-	-	-	0.38	-	-	0.38	0.38 Ethylene Oxide
Sterilization (S8 to S9)	-	-	-	-	-	0.37	-	-	0.37	0.37 Ethylene Oxide
Surface Coating	-	-	-	-	-	2.05	-	-	0.01	0.01 Methanol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	-	0.12	0.12 Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-	-
Boilers	0.17	0.67	0.67	0.05	8.78	0.48	7.38	10,602	0.17	0.16 Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	1,389	0.01	6.48E-03 Benzene
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	-	0.17	0.09 TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**19.57**	**13.94**	**11,991**	**1.23**	**0.75 Ethylene Oxide**

Appendix A: Potential Emission Calculations
Source Wide Ethylene Oxide (EO) Emissions by Facility

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Significant Permit Revision No.: 105-32055-00030
Reviewer: Sarah Street

Existing Sterilization Chamber (S1 through S7)	Stack Vent Identification #	Fraction of EO Usage	Maximum Uncontrolled Emissions (lbs/yr) (1)	Control Efficiency (%)	Maximum Controlled Emissions (lbs/yr)
Sterilization Chamber (Vacuum) Vents	PS01	0.9500	72,000.0	99.00%	720
Sterilization Chamber Exhaust Vents (Back vents)	SV01	0.0035	260.0	99.00%	2.6
Product Transfer	SV01	0.0021	1.56	0%	1.56
Aeration (HC1 through HC14)	HV01	0.0444	3,340.0	99.00%	33.4
Total (lbs/yr)	-	1.00	75,601.56	-	757.56
Total (tons/yr)	**-**	**-**	**37.80**	**-**	**0.38**

Notes
(1) The Maximum Uncontrolled Emissions were calculated as follows: Potential Emissions = Fraction of EO Usage x [Maximum Production (pallets/hr) x Average EO/Pallet x 8760 hrs/yr]
The Maximum Production and Average EO/Pallet is confidential information, pursuant to 326 IAC 17.1-4
Potential Emissions for Sterilization Chambers S1 through S7 taken from FESOP Second Renewal No. F105-27381-00030, issued August 24, 2009.

Proposed Revision (Units S8 and S9)	Stack Vent Identification #	Fraction of EO Usage	Maximum Uncontrolled Emissions (lbs/yr) (1)	Control Efficiency (%)	Maximum Controlled Emissions (lbs/yr)
Sterilization Chamber (Vacuum) Vents	PS01	0.9500	45,671.0	99.00%	456.71
Sterilization Chamber Exhaust Vents (Back vents) (2)	CEV01, 02	0.0035	168.0	0%	168
Product Transfer	-	0.0021	101.0	0%	101.00
Aeration (HC1 through HC14)	HV01	0.0444	2,135.0	99.00%	21.35
Total (lbs/yr)	-	1.00	48,075.00	-	747.06
Total (tons/yr)	**-**	**-**	**24.04**	**-**	**0.37**

Notes
(1) The Maximum Uncontrolled Emissions were calculated as follows: Potential Emissions = Fraction of EO Usage x [Maximum Production (pallets/hr) x Average EO/Pallet x 8760 hrs/yr]
The Maximum Production and Average EO/Pallet is confidential information, pursuant to 326 IAC 17.1-4

(2) With this proposed revision, the new sterilization chambers S8 & S9 are not required to control the sterilization chamber exhaust vents (back vents), pursuant to 40 CFR 63, Subpart O (National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Emissions Standards for Sterilization Facilities). The existing units, S1 through S7, are required to control the back vents pursuant to the source's 8-1-6 BACT for these units.

The size and production rate of these sterilization chambers is approved as confidential information, and has been submitted to IDEM, OAQ with this Significant Permit Revision application on June 28, 2012.

Potential to Emit after Significant Permit Revision
Sterilization Chambers S1 through S9

	Maximum Uncontrolled Emissions	Maximum Controlled Emissions
Total (lbs/yr)	123,676.56	1,504.62
Total (tons/yr)	**61.84**	**0.75**

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Appendix A: Emission Calculations
VOC and Particulate
From Surface Coating, Miscellaneous Cleaning Operations, Catheter Inpregnation, and Paclitaxel Treatment

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Significant Permit Revision No.: 105-32055-00030
Reviewer: Sarah Street

State Potential Emissions (uncontrolled):

Material (as applied)	Process	Density (Lb/Gal)	Weight % Volatile (H20& Organics)	Weight % Water	Weight % Organics	Volume % Water	Volume % Non-Vol (solids)	Maximum Gal of Mat. (gal/hr)	Pounds VOC per gallon of coating less water	Pounds VOC per gallon of coating	Potential VOC pounds per hour	Potential VOC pounds per day	Potential VOC tons per year	Particulate Potential ton/yr	lb VOC /gal solids	Transfer Efficiency
Surface Coating																
(Confidential)	Plastic Tubing & Metal Wiring	[redacted]							7.7	7.66	0.25	6.07	1.11	0.00	197.90	100.00%
(Confidential)	Plastic Tubing								6.5	6.51	0.21	5.16	0.94	0.00	N/A	100.00%
Miscellaneous Cleaning																
(Confidential)	Miscellaneous Cleaning	[redacted]							6.5	6.51	2.16	51.87	9.47	0.00	N/A	100.00%
Catheter Impregnation																
(Confidential)	Catheter Impregnation	[redacted]							1.2	1.20	0.03	0.68	0.12	0.00	N/A	100.00%
(Confidential)	Catheter Impregnation								7.5	7.50	0.18	4.24	0.77	0.00	N/A	100.00%
Paclitaxel Treatment																
(Confidential)	Paclitaxel Treatment	[redacted]							6.6	6.60	0.54	13.07	2.38	0.00	N/A	100.00%
(Confidential)	Paclitaxel Treatment								6.6	6.60	0.54	13.07	2.38	0.00	N/A	100.00%
Total State Potential Emissions:											**3.92**	**94.14**	**17.18**	**0.00**		

Federal Potential Emissions (controlled):

	Control Efficiency: VOC	Control Efficiency: PM	Controlled VOC lbs per Hour	Controlled VOC lbs per Day	Controlled VOC tons per Year	Controlled PM tons/yr
Total Federal Potential Emissions:	0.00%	0.00%	**3.92**	**94.14**	**17.18**	**0.00**

Note:
Shaded boxes indicate information is confidential.

Methodology:
Pounds of VOC per Gallon Coating less Water = (Density (lb/gal) * Weight % Organics) / (1-Volume % water)
Pounds of VOC per Gallon Coating = (Density (lb/gal) * Weight % Organics)
Potential VOC Pounds per Hour = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr)
Potential VOC Pounds per Day = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr) * (24 hr/day)
Potential VOC Tons per Year = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr) * (8760 hr/yr) * (1 ton/2000 lbs)
Particulate Potential Tons per Year = (units/hour) * (gal/unit) * (lbs/gal) * (1- Weight % Volatiles) * (1-Transfer efficiency) *(8760 hrs/yr) *(1 ton/2000 lbs)
Pounds VOC per Gallon of Solids = (Density (lbs/gal) * Weight % organics) / (Volume % solids) * Transfer Efficiency
Total = Worst Coating + Sum of all solvents used
Controlled emission rate = uncontrolled emission rate * (1 - control efficiency)

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Appendix A: Emission Calculations
Uncontrolled Surface Coating HAP Emissions - Potential to Emit

Company Name: **Cook Incorporated**
Address: **6330 North Matthews Drive, Ellettsville, Indiana 47429**
Significant Permit Revision No.: **105-32055-00030**
Reviewer: **Sarah Street**

Potential To Emit							
Material	Process	Density (lb/gal)	Maximum Gal of Mat. (gal/hr)	Weight % Methanol	Weight % MIBK	Methanol Emissions (tons/yr)	MIBK Emissions (tons/yr)
(Confidential)	Plastic Tubing & Metal Wiring					0.01	0.00
(Confidential)	Plastic Tubing					0.00	0.00
(Confidential)	Catheter Impregnation					0.12	0.00
						0.13	0.00
							0.13

Note:
Shaded boxes indicate information is confidential.

Methodology:
HAPs emission rate (tons/yr) = density (lb/gal) * (gal/unit) * (units/hour) * weight % HAP * % Flash Off * (8,760 hrs/yr) * (1 ton/2,000 lb)

Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100
Insignificant Combustion
Boilers
Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Significant Permit Revision No.: 105-32055-00030
Reviewer: Sarah Street

Unit ID	MMBtu/hr
C230-F	1.68
C231-F	1.68
C232-F	7.00
C233-F	0.85
C238-F	0.45
C239-F	1.26
C240-F	1.26
C241-F	2.1349
C242-F	2.1349
C246-F	1.50
C364-F	0.50
	20.45

Heat Input Capacity MMBtu/hr	HHV mmBtu / mmscf	Potential Throughput MMCF/yr
20.45	1020	175.6

	Pollutant						
	PM*	PM10*	direct PM2.5*	SO2	NOx	VOC	CO
Emission Factor in lb/MMCF	1.9	7.6	7.6	0.6	100 **see below	5.5	84
Potential Emission in tons/yr	0.17	0.67	0.67	0.05	8.78	0.48	7.38

*PM emission factor is filterable PM only. PM10 emission factor is filterable and condensable PM10 combined.
PM2.5 emission factor is filterable and condensable PM2.5 combined.
**Emission Factors for NOx: Uncontrolled = 100, Low NOx Burner = 50, Low NOx Burners/Flue gas recirculation = 32

	HAPs - Organics				
	Benzene	Dichlorobenzene	Formaldehyde	Hexane	Toluene
Emission Factor in lb/MMcf	2.1E-03	1.2E-03	7.5E-02	1.8E+00	3.4E-03
Potential Emission in tons/yr	1.844E-04	1.054E-04	6.586E-03	1.581E-01	2.986E-04

	HAPs - Metals				
	Lead	Cadmium	Chromium	Manganese	Nickel
Emission Factor in lb/MMcf	5.0E-04	1.1E-03	1.4E-03	3.8E-04	2.1E-03
Potential Emission in tons/yr	4.391E-05	9.660E-05	1.229E-04	3.337E-05	1.844E-04

	Greenhouse Gas		
	CO2	CH4	N2O
Emission Factor in lb/MMcf	120,000	2.3	2.2
Potential Emission in tons/yr	10,538	0.2	0.2
Summed Potential Emissions in tons/yr	10,538		
CO2e Total in tons/yr	10,602		

Methodology
All emission factors are based on normal firing.
MMBtu = 1,000,000 Btu
MMCF = 1,000,000 Cubic Feet of Gas
Emission Factors are from AP 42, Chapter 1.4, Tables 1.4-1, 1.4-2, 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03
Potential Throughput (MMCF) = Heat Input Capacity (MMBtu/hr) x 8,760 hrs/yr x 1 MMCF/1,020 MMBtu
Emission (tons/yr) = Throughput (MMCF/yr) x Emission Factor (lb/MMCF)/2,000 lb/ton
The five highest organic and metal HAPs emission factors are provided above.
Additional HAPs emission factors are available in AP-42, Chapter 1.4.
The N2O Emission Factor for uncontrolled is 2.2. The N2O Emission Factor for low Nox burner is 0.64.
Emission Factors are from AP 42, Table 1.4-2 SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03.
Global Warming Potentials (GWP) from Table A-1 of 40 CFR Part 98 Subpart A.
Emission (tons/yr) = Throughput (MMCF/yr) x Emission Factor (lb/MMCF)/2,000 lb/ton
CO2e (tons/yr) = CO2 Potential Emission ton/yr x CO2 GWP (1) + CH4 Potential Emission ton/yr x CH4 GWP (21) + N2O Potential Emission ton/yr x N2O GWP (310).

Appendix A: Emission Calculations
Large Reciprocating Internal Combustion Engines - Diesel Fuel
Output Rating (>600 HP)
Maximum Input Rate (>4.2 MMBtu/hr)

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Significant Permit Revision No.: 105-32055-00030
Reviewer: Sarah Street

Emissions calculated based on output rating (hp)

Output Horsepower Rating (hp)	4772.0
Maximum Hours Operated per Year	500
Potential Throughput (hp-hr/yr)	2,386,000
Sulfur Content (S) of Fuel (% by weight)	0.500

Emergency Diesel Generators:

Unit #1 (HP)	1850
Unit #2 (HP)	2922

	Pollutant						
	PM*	PM10*	direct PM2.5*	SO2	NOx	VOC	CO
Emission Factor in lb/hp-hr	7.00E-04	4.01E-04	4.01E-04	4.05E-03 *(.00809S)*	2.40E-02 **see below	7.05E-04	5.50E-03
Potential Emission in tons/yr	0.84	0.48	0.48	4.83	28.63	0.84	6.56

*PM10 emission factor in lb/hp-hr was calculated using the emission factor in lb/MMBtu and a brake specific fuel consumption of 7,000 Btu / hp-hr (AP-42 Table 3.3-1).
**NOx emission factor: uncontrolled = 0.024 lb/hp-hr, controlled by ignition timing retard = 0.013 lb/hp-hr

Hazardous Air Pollutants (HAPs)

	Pollutant						
	Benzene	Toluene	Xylene	Formaldehyde	Acetaldehyde	Acrolein	Total PAH HAPs***
Emission Factor in lb/hp-hr****	5.43E-06	1.97E-06	1.35E-06	5.52E-07	1.76E-07	5.52E-08	1.48E-06
Potential Emission in tons/yr	6.48E-03	2.35E-03	1.61E-03	6.59E-04	2.10E-04	6.58E-05	1.77E-03

***PAH = Polyaromatic Hydrocarbon (PAHs are considered HAPs, since they are considered Polycyclic Organic Matter)
****Emission factors in lb/hp-hr were calculated using emission factors in lb/MMBtu and a brake specific fuel consumption of 7,000 Btu / hp-hr (AP-42 Table 3.3-1).

Potential Emission of Total HAPs (tons/yr)	**1.31E-02**

Green House Gas Emissions (GHG)

	Pollutant		
	CO2	CH4	N2O
Emission Factor in lb/hp-hr	1.16E+00	6.35E-05	9.30E-06
Potential Emission in tons/yr	1.38E+03	7.57E-02	1.11E-02

Summed Potential Emissions in tons/yr	**1.38E+03**
CO2e Total in tons/yr	**1.39E+03**

Methodology
Emission Factors are from AP 42 (Supplement B 10/96) Tables 3.4-1 , 3.4-2, 3.4-3, and 3.4-4.
CH4 and N2O Emission Factor from 40 CFR 98 Subpart C Table C-2.
Global Warming Potentials (GWP) from Table A-1 of 40 CFR Part 98 Subpart A.
Potential Throughput (hp-hr/yr) = [Output Horsepower Rating (hp)] * [Maximum Hours Operated per Year]
Potential Emission (tons/yr) = [Potential Throughput (hp-hr/yr)] * [Emission Factor (lb/hp-hr)] / [2,000 lb/ton]
CO2e (tons/yr) = CO2 Potential Emission ton/yr x CO2 GWP (1) + CH4 Potential Emission ton/yr x CH4 GWP (21) + N2O Potential Emission ton/yr x N2O GWP (310).

Appendix A: Emission Calculations
Other Insignificant Activities

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Significant Permit Revision No.: 105-32055-00030
Reviewer: Sarah Street

The following emissions were calculated and approved with FESOP Second Renewal No. 105-27381-00030, issued August 24, 2009

Total Potential To Emit (tons/year)				
Emissions Generating Activity				
Pollutant	Assembly Operations	Package Prep	Marking, Printing	**TOTAL**
PM	0.14	0.00	0.00	0.14
PM10/PM2.5	0.14	0.00	0.00	0.14
SO2	0.00	0.00	0.00	0.00
NOx	0.00	0.00	0.00	0.00
VOC	0.11	0.18	0.03	0.32
CO	0.00	0.00	0.00	0.00
total HAPs	0.00	0.17	0.00	0.17
worst case single HAP	0.00	(TCE) 0.09	0.00	(TCE) 0.09

APPENDIX D

COMPLIANCE TEST PROTOCOL

Confidential Business Information

www.atlanticcompanies.com

Atlantic Design Engineers, Inc.
P.O. Box 1051
Sandwich, MA 02563

PERFORMANCE TEST PROTOCOL

Cook Sterilization System Compliance Test

Ellettsville, Indiana Sterilization Facility

Submitted To:

Indiana Department of Environmental Management
Office of Air Management
P.O. Box 6015
100 North Senate Avenue
IGCN, 10th Floor
Indianapolis, Indiana 46206-6015

Prepared For:

Cook Incorporated
6300 North Matthews Drive
Ellettsville, Indiana 47429

ADE Project No. 5450.12

June 20, 2018

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1.0 INTRODUCTION

1.1 Facility

Cook, Incorporated (Cook) operates a stationary medical device manufacturing and sterilization operation located at 6300 North Mathews Drive in Ellettsville, Indiana. Ethylene Oxide is used at the Cook facility to sterilize medical devices following manufacture before distribution. Cook was issued a Significant Permit Revision (F 105-32055-00030) on September 7, 2012 to their Federally Enforceable State Operating Permit (FESOP) which allowed Cook to expand the sterilizer operations through the addition of two new sterilizers designated as S-8 and S-9 to the existing sterilization operations at the facility.

1.2 Emissions control equipment

Cook's sterilization process utilizes a combination of wet acid scrubbing and chemisorption (dry bed reaction) to control ethylene oxide emissions from nine (9) sterilizers and fourteen (14) aeration rooms (hot cells).

I. Ethylene oxide emissions from sterilization chamber (vacuum) vents are controlled by a wet acid scrubber with a minimum control (removal) efficiency of 99%.

II. Sterilization chamber exhaust vents (back vents) from sterilizers S-1 through S-7 are controlled by a single dry bed reactor with a minimum control efficiency of 99%. Sterilizers, S-8 and S-9, operational since 2012 are by permit not required to have back vent emissions controlled.

III. Aeration room (hot cell) vents are controlled by a hybrid technology that consists of a wet acid pre-scrubber and three (3) dry bed reactor units operating in parallel.

The wet pre-scrubber in the aeration vent emission control system removes ethylene oxide with an efficiency of ~85%, with its principal function being to reduce the mass loading of ethylene oxide to the chemisorption medium in order to increase dry-bed media life and, accordingly, reduce bed replacement costs.

The wet acid scrubbers function by hydrolyzing ethylene oxide. The scrubbing medium is a sulfuric acid solution in which the acid is used as a catalyst. The reaction product is ethylene glycol.

The dry bed reactors (chemisorbers) remove ethylene oxide from gas streams via a gas phase chemical reaction with a granular solid. The solid medium is a proprietary copolymer of styrene and divinylbenzene in the form of small beads. Ethylene oxide gas

molecules contact the porous solid and react with active sites distributed throughout the solid matrix. The reaction product is an extended solid with ethylene oxide that is chemically bound to the solid medium.

1.3 Regulatory background

1.3.1 Operating Permit

The facility was constructed and has been operating in accordance with a Federally Enforceable State Operating Permit (FESOP) issued by the Indiana Department of Environmental Management (IDEM). The facility is operating in accordance with a FESOP Renewal, F 105-27381-00030, issued by the State of Indiana on August 24, 2009.

A Second Significant Revision to F 105-27381-00030 was approved by IDEM on September 7, 2012 (F 105-32055-00030) for a sterilization expansion for the two most recently installed sterilizers, S-8 and S-9, at the Cook sterilization facility.

In accordance with the FESOP and NESHAP requirements, Cook has conducted performance tests of the emissions control system on June 4, 1999, September 18th and 19th of 2003, and March 15, 2013. The results of these prior tests demonstrated that the performance standards specified in the permit and applicable requirements of the NESHAP were satisfied during both tests.

1.3.2 Compliance Requirements

A condition of Section D.1.5 of the Second Significant Permit Revision issued by IDEM is that Cook Medical perform performance testing at least once every five (5) years from the date of the most recent compliance demonstration.

Section D.1.5. of the permit revision imposes performance test requirements on the following control devices:

I. The primary wet acid scrubber, exhausting to stack PS01, controlling ethylene oxide emissions from the nine sterilization chambers (S1 through S9.)

II. The one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), exhausting to stack HV01, controlling ethylene oxide emissions from the fourteen (14) aeration rooms.

1.4 Quinquennial Testing Overview

Atlantic Design Engineers, Inc. (Atlantic) has been contracted by Cook Incorporated (Cook) to conduct the upcoming five (5) year scheduled performance test in accordance with the requirements of the Significant Permit Revision issued by IDEM on September 7, 2012. This emissions test protocol presents the proposed performance test procedures.

Performance testing of the emissions control system will be conducted using the procedures listed in 40 CFR 63.363 (Compliance and Performance Testing), 40 CFR 63.365 (Test Methods and Procedures), and 40 CFR 63.7 of subpart A, as well as the provisions of 326 IAC 3-6 (Source Sampling Procedures) as supplemented by the methods/procedures presented herein. Since several independent emission control systems are used to treat ethylene oxide emissions from multiple sources and operating sequences, the test program will be structured as follows to isolate and characterize emissions in accordance with each applicable standard:

1.4.1 Compliance Test #1: Sterilizer Chamber Vent Standard (SCV)

A sterilization chamber vent (vacuum pump) test will determine the performance efficiency of the primary wet acid scrubber. The current FESOP limits the production of the facility to a maximum of four (4) sterilizers that can be simultaneously discharged. The newly installed sterilizers, S-8 and S-9, along with two of the remaining seven sterilizers will be concurrently charged and evacuated to confirm emissions control system performance while the emissions control equipment is being charged at maximum ethylene oxide loadings. This procedure will satisfy both the testing of the new equipment as well as the largest sterilization chambers currently installed at the facility.

The performance efficiency of the primary wet acid scrubber will be determined for the first post-sterilization chamber evacuation from simultaneous discharge of the four sterilizers in accordance with 40 CFR 63.365 (b) and (c) (2). Subsequent SCV tests will be performed on sterilizers S-8 and S-9 individually as these are, by volume, the two largest sterilizers. Results will be based upon the average of three (empty chamber) sterilization runs.

This testing is required to ensure that the primary wet acid scrubber will control emissions from the Sterilizer Chamber Vents (SCVs) with at least 99% efficiency, and to ensure compliance with 326 IAC 8-1-6 (BACT) and 40 CFR Subpart O and also to confirm the FESOP (326 IAC 2-8) status of the source. The list of the original six sterilizers and the additional three sterilizers added since the last

emissions test are shown in Table 1 in Section 2.1.1 on page 4 of this Test Protocol.

1.4.2 Compliance Test #2-Aeration Room Vent Standard (ARV)

An aeration test will be run to evaluate the performance efficiency of the wet acid pre-scrubber/ dry bed reactor system while production materials are being aerated. Production materials from at least five recent sterilizer loads will be aerated in a normal manner. The aeration age of each load may vary by up to one hour since simultaneous discharge of materials from several sterilizers is not encountered during routine production.

Three back-to-back runs of one-hour duration each will constitute the aeration test per 40 CFR 63.365 (d) (1), (2) and (3). Results will be reported as the arithmetic average control efficiency for the three runs.

The controls for the aeration rooms are required to have an efficiency of at least 99%. The performance testing is required to ensure compliance with 326 IAC 8-1-6 (BACT) and 40 CFR Subpart O as well as to confirm the FESOP (326 IAC 2-8) status of the source.

1.4.3 Chamber Exhaust Vent (Back Vent) Standard – No Testing Required

The existing sterilization chamber exhaust vents (back vents) for units S-1 through S-7 are controlled by a single dry bed reactor and have existing monitoring and record keeping requirements sufficient to determine compliance. The FESOP revision issued in 2012 specifically excluded repeat testing of the sterilization chamber exhaust vents as they were tested as part of the initial performance test and the permit further states:

> The existing sterilization chamber exhaust vents (back vents) for units S-1 through S-7, controlled by one (1) single non-regenerable dry-bed reactor, have existing monitoring and record keeping requirements sufficient to determine compliance; further, the back vents have minimal ethylene oxide emissions.

1.5 March 15, 2013 Compliance Testing & Performance Test Report

Compliance testing for the sterilization system expansion was conducted on March 15, 2013 with on-site review and inspection by Steve Friend of the IDEM Office of Air quality.

1.5.1 Testing Results

The following control efficiencies of the EO emission control systems for the Sterilizer Chamber Vent (SCV) and Aeration Room Vents (ARV) were calculated, as shown within Cook's April 23, 2013 Performance Test Report.

I. Average SCV Reduction Efficiency of 99.999%

II. Average ARV Reduction Efficiency of 99.854%

III. Average Outlet Concentration <0.01 ppm

1.5.2 Conclusions

Results of the March 15, 2013 on-site emissions testing at the Ellettsville sterilization facility demonstrated that:

I. Cook's emissions control equipment, as tested, meets the standards as set forth in the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Sterilization Facilities (Subpart O).

II. Cook's emissions control equipment, as tested, meets the conditions of Cook's State Operating Permit number F 105-32055-00030 issued by the Indiana Department of Environmental Management.

2.0 STERILIZATION EQUIPMENT AND PROCESS DESCRIPTION

2.1 Sterilization Equipment

Cook's sterilization operations consist of the operation of nine (9) sterilization chambers and fourteen (14) aeration rooms (hot cells) to handle EO off gassing from the sterilized product after sterilization is completed.

2.1.1 Sterilization Chambers (Sterilizers)

Cook is permitted to operate nine (9) gas sterilization chambers. The sterilization operations are presently conducted with 100% EO as a sterilant. The sterilizers are designed to operate independently in a batch mode. The sterilizer chamber sizes are shown in the following table:

Table 1
Existing Sterilizers and Specifications

Chamber Number	Internal Volume (cubic feet)	Capacity (# of pallets)	Current Status
1	512	**3**	Operational
2	**512**	**3**	Operational
3	**512**	**3**	Operational
4	**512**	**3**	Operational
5	**175**	**1**	Operational
6	**350**	**2**	Operational
7	**512**	**3**	Operational
8	**1240**	**8**	Operational
9	**1240**	**8**	Operational

Each sterilization chamber is evacuated at a nominal flow rate of [redacted] by a dedicated, rotary cam nitrogen sealed dry vacuum pump. The vacuum pumps are manifolded to deliver all evacuated gases to the primary wet acid scrubber for treatment prior to discharge to the atmosphere.

During the chamber exhaust vent (back vent) cycle, the back vents for sterilizers S-8 and S-9 are uncontrolled and directly exhausted to atmosphere.

2.1.2 Aeration Rooms

Cook is permitted to operate fourteen (14) aeration rooms ("cells") to degas residual ethylene oxide gases remaining in products from the sterilization process. All the aeration cells are identical, with individual internal volumes of approximately [redacted] and a capacity of [redacted]

Each cell has two opposing doors; an access door through which pallets of recently sterilized product are brought into the cell for aeration, and an exit door through which de-gassed product is removed from the cell after completion of the aeration process.

Each aeration cell has a heating/ventilation system that:

I. maintains the cell at elevated temperature [redacted] to promote evolution of residual gases;

II. maintains a slightly negative pressure within the cell (to prevent escape of fugitive gases to occupied work spaces);

III. provides a well-mixed cell environment;

IV. exhausts cell air to a wet acid pre-scrubber and/or dry bed reactor emission control system at a flow rate of [redacted] per cell (cfm/cell); and,

V. delivers fresh, filtered make-up air to the cell.

2.2 Sterilization Process

Gas sterilization is a batch process that uses a sealed chamber (sterilizer) in which non-sterile products are exposed to ethylene oxide gas in order to destroy microorganisms and render the products sterile. Cook currently uses 100% EO as the sterilant gas in this procedure.

Since minor operational changes are continually being made to accommodate the needs of the wide variety of medical products that Cook produces, the procedure described below is typical, and actual sterilization conditions such as contact time and temperatures may vary slightly.

The sterilization procedure currently used by Cook is described as follows:

STEP 1. Loading

Non-sterile products from post-production packaging operations are palletized and transferred into a sterilization chamber and the door is closed. The products are preconditioned in a moist environment, readying them for sterilization. One (1) to eight (8) pallets of preconditioned products are sterilized at a time.

STEP 2. Conditioning

The chamber is then partially evacuated and the chamber is conditioned to optimum relative humidity and temperature. This serves to further acclimate the products to the conditions to which they will be exposed during sterilization, thus increasing the effectiveness of the process.

STEP 3. Sterilization

Following conditioning, the sterilizer is further evacuated and charged with sterilant gas to a maximum charge density of between [redacted] of ethylene oxide. These conditions are maintained for an exposure period of [redacted] to completely destroy microorganisms that may be present.

STEP 4. Air Washing

Following the exposure period, the sterilization chamber is flushed ("washed") with air multiple times to remove the sterilant gas. During air washing, the chamber is repeatedly evacuated with a sealed loop vacuum pump and then flooded with air.

STEP 5. Back venting

Following air washing, the sterilization chamber door is "cracked" open and the back vent blower is operated to exhaust residual ethylene oxide from the chamber. This operation is conducted for approximately [redacted] Back venting is analogous to the Sterilization Chamber Exhaust Vent cycle identified in EPA's MACT Standard. Residual sterilant gas evolved from the product during this step is discharged to the emissions control system, i.e., dry bed reactor, from sterilizers S-1 through S-7 and to atmosphere through dedicated exhaust stacks from sterilizers S-8 and S-9.

STEP 6. Product Transfer

Following back venting, the products are manually transferred from the sterilization chamber to the aeration room. One pallet is transferred at a time. D[redacted]

STEP 7. Aeration

The sterilized products are further degassed in the aeration room for a minimum duration of [redacted]. This step allows residual ethylene oxide retained in the sterilized products to diffuse out, rendering the products essentially free of ethylene oxide. Aeration room air is treated by a wet acid (pre)scrubber for the first several hours [redacted] and then a dry bed reactor. For the remainder of the aeration time, aeration room air is discharged directly to the dry bed reactor. The treated discharge flow from the dry bed reactor is exhausted to the environment to maintain a negative pressure in the aeration room.

2.3 EMISSIONS CONTROL SYSTEM

The emission control system for Cook's sterilization process consists of two (2) wet acid scrubbers and four (4) dry bed reactors. Advanced Air Technologies, Inc. of Corunna, MI manufactured all of the sterilization emissions control equipment. The wet-acid scrubbers are model Safe Cell II and the dry bed reactors model DR-490A.

Each wet-acid scrubber functions by hydrolyzing ethylene oxide into ethylene glycol. The scrubbing medium is a sulfuric acid solution in which the acid acts as a catalyst.

The four (4) dry bed reactors (chemisorbers) remove ethylene oxide from gas streams via a gas phase chemical reaction with a granular solid. The solid medium is a proprietary copolymer of styrene and divinylbenzene in the form of small beads. Ethylene oxide gas molecules contact the porous solid and react with active sites distributed throughout the solid matrix. The small size of the particles increases the surface area to volume ratio of the solid and enhances diffusion of gas through and contact with active sites in the porous matrix. The reaction product is an extended solid with ethylene oxide that is chemically bound to the solid medium.

I. Ethylene oxide emissions from sterilization chamber (vacuum) vents are controlled by a wet acid scrubber with a minimum control (removal) efficiency of 99%.

II. Aeration room (hot cell) vents are controlled by a hybrid technology that consists of a wet acid pre-scrubber and three (3) dry bed reactor units operating in parallel.

III. Sterilization chamber exhaust vents (back vents) are controlled by a single dry bed reactor with a minimum control efficiency of 99% for sterilizers S1-S7. Sterilizer back vents (CEVs) are exhausted directly to the atmosphere. Sterilizers S-8 and S-9 are uncontrolled and are directly exhausted through dedicated stacks to the atmosphere

2.3.1 Sterilization Chamber Vent (SCV)

One wet-acid scrubber, [redacted] treats all sterilization chamber vent emissions. This scrubber is designated as the Primary Scrubber on the Block Flow Diagram (Figure 1) attached to this document.

2.3.2 Aeration Room Vent (ARV)

A second wet-acid scrubber, [redacted] provides primary control of the aeration room vent (ARV) emissions. This scrubber is designated as the Hot Cell Pre-Scrubber on the Block Flow Diagram. Exhaust from the Hot Cell Pre-Scrubber passes to three dry bed reactors for final removal of any remaining ethylene oxide in the gas stream. The three reactors are ducted in parallel and have a combined rating of [redacted] These are designated as the Hot Cell Dry Bed Reactors "A", "B"' and "C".

Initially, aeration room exhaust gases are directed to the Hot Cell Pre-Scrubber to remove the bulk of the ethylene oxide prior to passing the exhaust through the Hot Cell Dry Bed Reactors. This allows the wet acid scrubber to handle most of the ethylene oxide load and extends the useful life of the adsorbing media in the dry bed reactor.

After progressing to a point in the degassing process where ethylene oxide emissions become substantially lower [redacted] the aeration room vent emissions are diverted to and treated solely by the Hot Cell Dry Bed reactors.

2.3.3 Chamber Exhaust Vent (CEV)

Although CEV emissions control standards have been eliminated from the NESHAP (Federal Register / Vol. 66, No 213, November 2, 2001), the Cook FESOP requires that these emissions be controlled for Sterilizers S-1 through S-7. A single dry bed unit designated as the Exhaust Vent Reactor is used for CEV emissions control.

3.0 PROPOSED PERFORMANCE TESTING

Performance testing of the emission control system will be conducted in accordance with applicable portions of 40 CFR 63.363, Compliance and Performance Testing, and 40 CFR 63.365, Test Methods and Procedures, and supplemented by the methods / procedures presented herein. As described in Section 1.0, this Test Protocol covers compliance demonstrations of two separate emissions control standards in accordance with the provisions of the Significant Permit Revision issued by IDEM on September 7, 2012.

To demonstrate compliance, test results will be compared with performance requirements specified in the NESHAP standard and Cook's operating permit.

3.1 Compliance Test No. 1: Sterilization Chamber Vent (SCV)

3.1.1 SCV Emissions Control Standard

For the Sterilization Chamber Vent, an emissions reduction of at least 99% is specified in the FESOP No. 105-29042-00030 issued by IDEM for the Cook facility.

3.1.2 SCV Sampling Methodology

The initial performance test run will be for the maximum operational capacity allowed under the IDEM permit of four (4) sterilizers discharging simultaneously from the Sterilizer Chamber Vents to the wet scrubber unit.

The two (2) largest sterilizers by volume, S-8 and S-9, along with the two of the remaining originally permitted seven sterilizers will be tested without pallets of product in the chambers at normal operating conditions, e.g., temperature and pressure, by charging the chambers with ethylene oxide at the maximum charge density of [redacted] After a brief stabilization period to simulate the normal sterilization (exposure) cycle, the Sterilization Chamber Vent (SCV) cycle will be initiated by simultaneously evacuating all sterilizers.

Sampling and measurements will continue throughout the initial post-sterilization evacuation cycles. Outlet samples will be continuously collected, with flow measurements recorded at five (5) minute intervals. The four sterilizers have initial post-sterilization evacuation durations ranging from [redacted] for Sterilizer S-5 to [redacted] for Sterilizers S8 and S9.

During SCV sampling, the following data will be recorded:

I. Initiation and termination time for each sequence;

II. Sterilizer pressure, initial and at beginning/end of each evacuation (each sterilizer);

III. Sterilizer temperature (each sterilizer), at initial charge and at the beginning and end of initial SCV evacuation;

IV. Scrubber liquid level; and,

V. Ethylene Oxide (EO) gas charge for each sterilizer

During sampling, the following additional data will be established by GC analysis, flow measurements, or engineering calculations (refer to Section 5.5):

I. Volumetric flow rate at scrubber inlet;

II. Concentration of ethylene oxide, in parts per million by volume (ppmv) of primary wet acid scrubber inlet gases;

III. Volumetric flow rate of exhaust gases from the primary wet acid scrubber; and,

IV. Concentration of ethylene oxide, in parts per million by volume (ppmv) in exhaust gases from the primary wet acid scrubber.

Due to health and safety considerations, the EO concentrations and exhaust gas flows from the initial Sterilizer Chamber Vent evacuation will be determined by application of the Ideal Gas Law, utilizing measured sterilizer process conditions, i.e., pressure, temperature, and sterilizer free volume.

The foregoing data will be used to evaluate the performance efficiency of the primary (sterilization) wet acid scrubber. The performance test results will be based upon the arithmetic averaging of three sterilization test runs.

The subsequent test runs, test run two and three, will each be performed with a single sterilizer operating.

This sampling methodology was selected to demonstrate compliance with the SCV standard in the Cook FESOP and will evaluate system performance under the widest possible range, i.e., at maximum allowed by the current FESOP (four sterilizers) and minimum allowable (single sterilizer) ethylene oxide concentrations.

3.2 Compliance Test No. 2: Aeration Room Vent (ARV)

An Aeration Room Vent (ARV) test will be conducted to evaluate the performance efficiency of the hybrid ethylene oxide control system while production materials are being aerated. Each aeration room has two (2) exhaust ducts. One exhaust duct connects all aeration cells to a common manifold (Header A) which exhausts to the wet acid pre-scrubber, followed by the dry bed reactor system. The second exhaust duct connects all aeration cells to a separate manifold (Header B) that bypasses the wet acid pre-scrubber and exhausts directly to the (3) dry bed reactor system.

The configurations of the ARV headers are depicted in the Block Flow Diagram (Appendix A).

3.2.1 ARV Emissions Control Standard

Under Section 63.362 of the NESHAP, the emission standard for the Aeration Room Vent is specified as either:

I. An emission reduction of 99%, or

II. A concentration limit of 1 ppmv, whichever is less stringent.

Cook has elected to control ARV emissions to an emission reduction of 99% from the outlet of the Hot Cell Dry Bed Reactors as specified in the FESOP permit.

3.2.2 Phase I Control: Primary ARV Emissions (Header A)

To test the first phase of the aeration cycle (Header A), three of the operating aeration rooms (aeration cells) will be fully loaded with freshly sterilized product from the any of the four operating sterilizers (a total of 9 pallets). All exhaust gases from the three aeration cells will be evacuated using Header A only (exhaust gases pass through the Hot Cell Pre-Scrubber followed by the (3) parallel Hot Cell Reactors (A, B and C).

For a time period of one hour, samples will be collected into Cali-5-Bond™ bags from the inlet of the wet-acid pre-scrubber and outlet of the Hot Cell Reactors. Results will be reported as the arithmetic average control efficiency calculated for the three (3) test runs.

3.2.3 Phase II Control: Secondary ARV Emissions (Header B)

After completion of ARV Phase I testing, the Aeration cells that have been aerating the longest will be exhausted into Header B (directly to the three Hot Cell Dry Bed Reactors). Another set of one (1) hour samples will be taken from the Hot Cell Dry Bed Reactor inlet and outlet. Test results will be reported as the arithmetic average control efficiency calculated for the three (3) test runs.

During ARV testing (Phases I and II), the following data will be recorded:

I. Exhaust duct configuration for each of the aeration cells involved in the test (i.e. Header A or B),

II. Pre-scrubber liquid level, and

III. Number of pallets in each aeration cell.

IV. In addition, the following data will be established by sampling / flow measurements:

V. Concentration of ethylene oxide, in parts per million by volume (ppmv) in control system inlet gases,

VI. Concentration of ethylene oxide, in parts per million by volume (ppmv) in dry bed reactor system outlet gases, and,

VII. Volumetric flow rate of dry bed reactor system outlet duct.

4.0 COMPLIANCE REQUIREMENTS

The ethylene oxide (EO) gas-sterilization systems at Cook are being tested to demonstrate compliance with federal requirements contained in 40 CFR 63, Subpart O (NESHAP), and with the (FESOP) permit conditions granted by the Indiana Department of Environmental Management. In order to do so, the following criteria must be met:

I. The sterilizer exhaust (sterilization chamber vent) must be directed to control equipment with an EO emission reduction efficiency of at least 99% (NESHAP);

II. The aeration room exhaust must be reduced by 99%.

5.0 TEST METHODS

5.1 Introduction

The testing procedures outlined herein are based on United States Environmental Protection Agency (EPA) Method 18: Measurement Of Gaseous Organic Compound Emissions By Gas Chromatography).

Sampling ports will be located in accordance with EPA Reference Method 1.

Due to health and safety considerations, the EO concentrations and exhaust gas flows from the initial Sterilizer Chamber Vent evacuation will be calculated using the estimation/calculation techniques outlined in this section.

5.2 Volumetric Flow Measurement

Flow rates will be measured in accordance with USEPA Reference Method 2C using a standard pitot tube and an inclined-oil manometer.

Exhaust gas composition will be assumed to be air and small amounts of water vapor. Water vapor will be negligible, about 3 percent for the inlet and the outlet. Temperature measurements will be obtained from a thermocouple attached to the sampling probe.

5.3 Control Efficiency And Mass Emissions Measurement

5.3.1 Sterilizer Chamber Vent (SCV) Testing

During the Sterilizer Chamber Vent cycle, the mass of EO vented to the inlet of the Primary wet-acid scrubber will be determined through Ideal Gas Law calculations based on the conditions of the sterilization chamber immediately after it has been charged with sterilant gas.

The residual mass of ethylene oxide in the sterilizer will also be determined using ideal gas law calculations based upon the conditions in the chamber after the completion of the first evacuation. The mass of EO charged to the sterilization chamber and the residual mass of EO in the sterilizer after the first evacuation will be determined using Equation One, shown in section 5.5.1.

The mass of EO vented from the outlet of the Primary wet acid scrubber will be determined by sampling and flow measurements. A continuous bag sample will be taken during the entire cycle, and flow measurements will be taken and recorded at five minute intervals. The mass will be determined using Equation Two shown in section 5.5.2.

Mass-mass control efficiency of EO during the Sterilizer Chamber Vent cycle will be determined by comparing the calculated mass of EO to the system inlet to the measured mass of EO from the system outlet using Equation Five shown in section 5.5.5.

5.3.2 Aeration Room Vent (ARV) Testing

5.3.2.1 Phase I ARV Performance

During the first phase of the aeration room vent cycle, when gas flow is directed through the Hot Cell Pre-Scrubber to the Hot Cell Reactors utilizing Header A, the system inlet (Hot Cell Pre-Scrubber) and outlet (Hot Cell Reactors) will be sampled continuously during the entire first hour of the cycle. Flow measurements will be taken and recorded at five minute intervals.

The mass of EO emitted from the inlet and outlet of the emission control system will be determined by using Equation Four shown in section 5.5.4.

5.3.2.2 Phase II ARV Performance

During the second phase of the aeration room vent cycle, when gas bypasses the Hot Cell Pre-Scrubber and flows directly to the Hot Cell Reactors utilizing Header B, the EO concentration at the inlet and outlet of the hot cell reactors will be sampled for the entire first hour of the cycle. The mass will be determined using Equation Four shown in section 5.5.4.

During both Phases I and II, the Aeration Room Vent exhaust shall be reduced by 99%.

5.4 GC Injection

5.4.1 Gas Chromatograph

EO samples will be analyzed by an SRI, Model 8610C, portable gas chromatograph (GC), with the following applications: programmable column oven temperature from ambient to 400°C, mount up to six detectors and five injectors, control of up to 16 heated zones, three gas sampling valves, and seven EPC gas pressures. Up to six (6) detectors, from a choice of sixteen (16), can be mounted simultaneously. The airbath oven can hold a standard 7-inch diameter megabore column cage, or multiple columns with smaller coil sizes. A flame ionization detector (FID) will be used to quantify high-level EO emissions, and a

photoionization detector (PID) will be used to quantify low-level EO emissions at the emission-control device outlet.

Source gas samples will be injected into a Gas Chromatograph (GC) equipped with a sampling loop containing a volume of approximately 2cc and maintained at 100°C.

5.4.2 GC Calibration Standards

The FID will be calibrated for mid-range part-per-million-by-volume (ppmv) level analyses using gas proportions similar to the following:

1) 1,000 ppmv EtO, balance nitrogen
2) 100 ppmv EtO, balance nitrogen
3) 50 ppmv EtO, balance nitrogen (audit gas)
4) 10 ppmv EtO, balance nitrogen

The PID will be calibrated for low-range ppmv level analyses using gas proportions similar to the following:

1) 100 ppmv EtO, balance nitrogen
2) 50 ppmv EtO, balance nitrogen (audit gas)
3) 10 ppmv EtO, balance nitrogen
4) 1 ppmv EtO, balance nitrogen

Each of these calibration standards will be in a separate, certified manufacturer's cylinder. Copies of the calibration gas laboratory certificates will be included with the final report.

5.5 Control-Efficiency / Mass-Emissions Calculations

5.5.1 Calculation of Mass by Ideal Gas Law

The mass of EO will be determined in accordance with 40 CFR 63.363, (b) (1) (i) (c), the sterilization chamber prior to Sterilizer Chamber Venting by using the following equation:

EQUATION 1 $$W_C = \frac{(MW)(m)(P)(V)}{(R)(T)}$$

Where:

Wc	=	*Mass of Ethylene Oxide charged, lbm*
MW	=	*Molecular weight of Ethylene Oxide (44.05 lb/mol)*
M	=	*Mole fraction of EO @ 44.05 / $W_{\%EO}$ = 99.97%*
P	=	*Chamber pressure, psia*
V	=	*Chamber volume, ft^3*
R	=	*Gas constant, 10.73 psia x ft^3 / mole x ^oR*
T	=	*Temperature, ^oR*

5.5.2 Residual Charge Mass

The residual mass of ethylene oxide in the sterilizer (Wr) will be determined by recording the chamber temperature, pressure, and volume after the completion of the first evacuation and using the following equation:

EQUATION 2 $$W_r = \frac{(MW)(m)(P)(V)}{(R)(T)}$$

5.5.3 Inlet Mass to Control System

The total mass of ethylene oxide to the inlet to the control device (Wi) will be calculated by subtracting the residual mass (Wr) calculated with Equation 2 from the charged weight (Wc) calculated by Equation 1.

EQUATION 3 $$W_i = W_c - W_r$$

5.5.4 Outlet Mass from Control System

During the sterilizer exhaust cycle, the mass of ethylene oxide emitted from the control device outlet (Wo) shall be calculated by measuring the flow rate through the control device exhaust continuously during the first evacuation using procedures found in 40 CFR part 60, Test Methods 2, 2A, 2C, or 2D, as appropriate. Flow rates will be recorded at approximately 1-minute intervals throughout the test cycle, taking the first reading within 15 seconds after time zero, defined at the moment when the pressure in the sterilizer is released.

The concentration of ethylene oxide will be determined by the application of Test Method 18 using an on-site gas chromatograph. The outlet mass from the control system will be calculated by the following equation:

EQUATION 4

$$W_o = \frac{\left(VolFlow\ \frac{ft^3}{min}\right)\left(T_c\ \frac{min}{cycle}\right)\left(Mol.Wt.\frac{lbs}{mol}\right)\left(ppmv\ \frac{ppm\ EO}{10^6}\right)}{(Mol.Vol.)}$$

Where:

VolFlow	=	*Corrected volumetric flow rate (DCFM), standard cubic feet per minute at 68^0F and 1 atm pressure (29.92" Hg)*
T_c	=	*Total Cycle Time, minutes*
MolWt	=	*44.05 pounds of EO per pound mole*
Ppmv	=	*Ppm EO concentration converted parts per million by volume via 10^6 conversion factor, ppmv per "cubic foot per cubic foot"*
MolVol	=	*385.32 cubic feet per pound mole at standard conditions of one atmosphere and 68^0F*

Equation 4 will be used to calculate the inlet and outlet mass numbers for both the Primary and Secondary Aeration Room Vent Control efficiency calculations.

5.5.5 Control Device Efficiency

The efficiency of the control device will be calculated with the following equation:

EQUATION 5

$$C_E = \frac{(W_i - W_o)}{(W_i\ x\ 100)}$$

Where:

C	=	*Percent efficiency*
W_I	=	*Mass flow rate into control device*
W_O	=	*Mass flow rate out of the control device*

The calculated test performance results using the above equations will be presented in the final test report.

6.0 QUALITY ASSURANCE / QUALITY CONTROL

6.1 Field Testing

Prior to initiating on-site analytical work, a system blank will be analyzed to insure that the sampling system is free of EO. Air will be drawn through the sampling system line to the GC for analysis. At the start of analytic work, the sampling system will be leaked-checked at a vacuum of 15 inches of Mercury.

After the sampling system is determined to be clean, a sample of source gas will be injected into the sampling system and analyzed to determine the concentration of any residual EO present in the sample.

The following items are being confirmed for the field test procedures:

I. The initial Sterilizer Chamber Vent (SCV) compliance test run will be performed for the simultaneous vacuum pump discharge of four (4) sterilization chambers including the most recently installed sterilizers, S8 and S9.

II. The sterilizer vacuum pump discharge and aeration room exhaust flow rates will be monitored approximately every minute during the testing. A spreadsheet will be maintained during the test runs of the pressure differentials (ΔP) at one (1) minute intervals.

III. Each test run will include a minimum of five (5) direct injections per the Method 18 complete test requirement.

IV. Traverses will be performed prior to the performance test to determine the points of average flow (centroids). The flow measurements during the test will be taken at these exact points of average velocity during the compliance test.

V. The wet scrubber liquor levels will be recorded during the performance test.

VI. The efficiency calculations for the performance test runs will be completed assuming 3% ambient exhaust moisture contents (worst case scenario).

VII. Gas Chromatograph calibrations will be performed with on-site calibration gases following Method 18 procedures.

VIII. Recovery studies will be performed on the injection lines per Method 18 requirements.

IX. During the Aeration Room Vent (ARV) test runs inlet and outlet direction injection sampling will simultaneously be performed on the "A" and "B" inlet headers and the Dry Bed Reactors outlet stack.

6.2 Calibration Procedures

The calibration of all applicable manual sampling equipment will generally follow the QA / QC procedures in 40 CFR 60, the EPA “Quality Assurance Handbook,” Volume III,

APTA0576, and all applicable equipment manufacturers procedures. If sampling procedures differ from standard EPA methods, these variations will be noted.

The GC system will be calibrated at the beginning and conclusion of each day's testing. Each of the calibration standards will be taken from a separate, certified manufacturer's cylinder.

All calibration gases and support gases will be of the highest purity and quality available. A copy of the laboratory certification for each calibration gas will be included in the final report. Calibration curves will be generated using a least square linear regression.

7.0 TEST REPORT

The test results will be summarized in a written report. This report will be submitted to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch
Office of Air Quality
100 North Senate Avenue, IGCN 1003
Indianapolis, Indiana 46204-2251.

The report will include results for EO control reduction / efficiency of each emission-control system and mass emissions of EO to the atmosphere from the emission-controls.

I. All reports will undergo a tiered review.

II. The initial review of the report and calculations will be performed by the report author or project manager.

III. The second review is performed by another engineer or scientist.

The final review will be performed by a manager, a senior scientist, or a senior engineer prior to issuing the final report.

The reviewers will all sign the final report anticipated to contain the following:

I. Summary tables with comparisons of the test results to permit requirements;

II. Copies of all intermediate data tables and calculation worksheets;

III. Copies of all GC chromatograms from calibration runs and sample injections; and

IV. Laboratory calibration certificates for all calibration gases and all applicable measurement instruments.

APPENDIX E

PHOTOGRAPHS AND FIELD REPORT

[redacted]

FIELD REPORT

TO: Cook Sterilization Facility, Ellettsville, IN **DATE**: July 27, 2018

JOB NO: 5450.12

PROJECT NAME: Quinquennial Compliance Test – 2018

PRESENT AT SITE:
Simon Thomas & Zachary Thomas of Atlantic Design Engineers
Daniel Kremer of ECSi, Inc.
Art Harris, Jared Prow, and Brad Stout of Cook Inc.

LOCATION: 6300 North Matthews Drive, Ellettsville, IN

CONTRACTOR(S): Atlantic Design Engineers, ECSi, Cook Inc.

OWNER: Cook Incorporated

The following was noted during source testing activities:

Atlantic Design Engineers, Inc. (Atlantic) and ECSi arrived on-site at 8:00 AM to begin calibration of the Gas Chromatograph following Method 18 using 1 ppm, 10 ppm and 100 ppm calibration gas. Calibration was completed by 8:45 AM. Dan Kremer or ECSi then began inspection of testing locations, sample points, flow meters, etc. prior to initiating SCV Test #1. See the attached pictures for SCV & ARV sampling points.

Scrubber tank levels were measured at 9:06 AM and were as follows:

- Common Tank – 73.25”
- Scrubber Tank – 100.5”
- Aeration Tank – 103.0”

SCV Test #1

SCV Test#1 is proposed as the first test run of the compliance test. The four-sterilizer evacuation included Sterilizer 1 ([redacted] Cubic Feet), Sterilizer 4 ([redacted] cubic feet), Sterilizer 8 ([redacted] cubic feet) and Sterilizer 9 ([redacted] cubic feet). The SCV Test began at 9:57 am and sampling continued every minute for the 18-minute Sterilant Removal Phase. The following was noted during the sampling period:

a. Ambient Moisture (percent)
b. Header Stack flowrate (ft/s)
c. Pressure (inHg)
d. Stack Volume (m^3)

e. Ambient Temperature (Rankine)
f. Outlet Concentration of Eto
g. Scrubber Liquid Level (Pre and Post test)
h. Initial EO charge by sterilizer

Outlet concentrations ranged from non detect to 146ppm. See the attached SCV Run #1 results summary. Removal efficiency was calculated to be 99.98%.

ARV Test #1-#3

For ARV Test #1, aeration started at 11:25am and the first GC injection was completed at 11:28am. ARV Test #2 was initiated at 12:25pm and ARV Test #3 was initiated at 1:25pm.

The following conditions were noted every 60 seconds throughout each 55-minute testing period:

a. ΔP (inHg)
b. $\sqrt{\Delta P}$
c. Temperature (ºF)

The following was collected on five minutes intervals throughout each 55-minute testing period:

a. Inlet and Outlet Eto concentrations

After completion of the three consecutive aeration-sampling events, reduction efficiency was calculated to be 99.86%. See the attached datasheets.

SCV Test #2

SCV Test#2 included the sterilant removal phase from Sterilizer 8 ([redacted] cubic feet). The SCV Test began at 2:36 pm and sampling continued every minute throughout the 18-minute Sterilant Removal Phase. The same criteria were noted as during SCV Test #1.

Outlet concentrations did not exceed detection limits of the GC. See the attached SCV Run #2 results summary. Removal efficiency was calculated to be 99.99%.

SCV Test #3

SCV Test#3 included the sterilant removal phase from Sterilizer 9 ([redacted] cubic feet). The SCV Test began at 2:58pm and sampling continued every minute throughout the 18-minute Sterilant Removal Phase. The same criteria were noted as during SCV Test #1.

Outlet concentrations did not exceed detection limits of the GC. See the attached SCV Run #3 results summary. Removal efficiency was calculated to be 99.89%.

Scrubber tank levels were again measured at 3:46 PM and were as follows:

- Common Tank – 73.25”
- Scrubber Tank – 100.5”
- Aeration Tank – 103.0”

Test Schedule Summary (July 27, 2018):

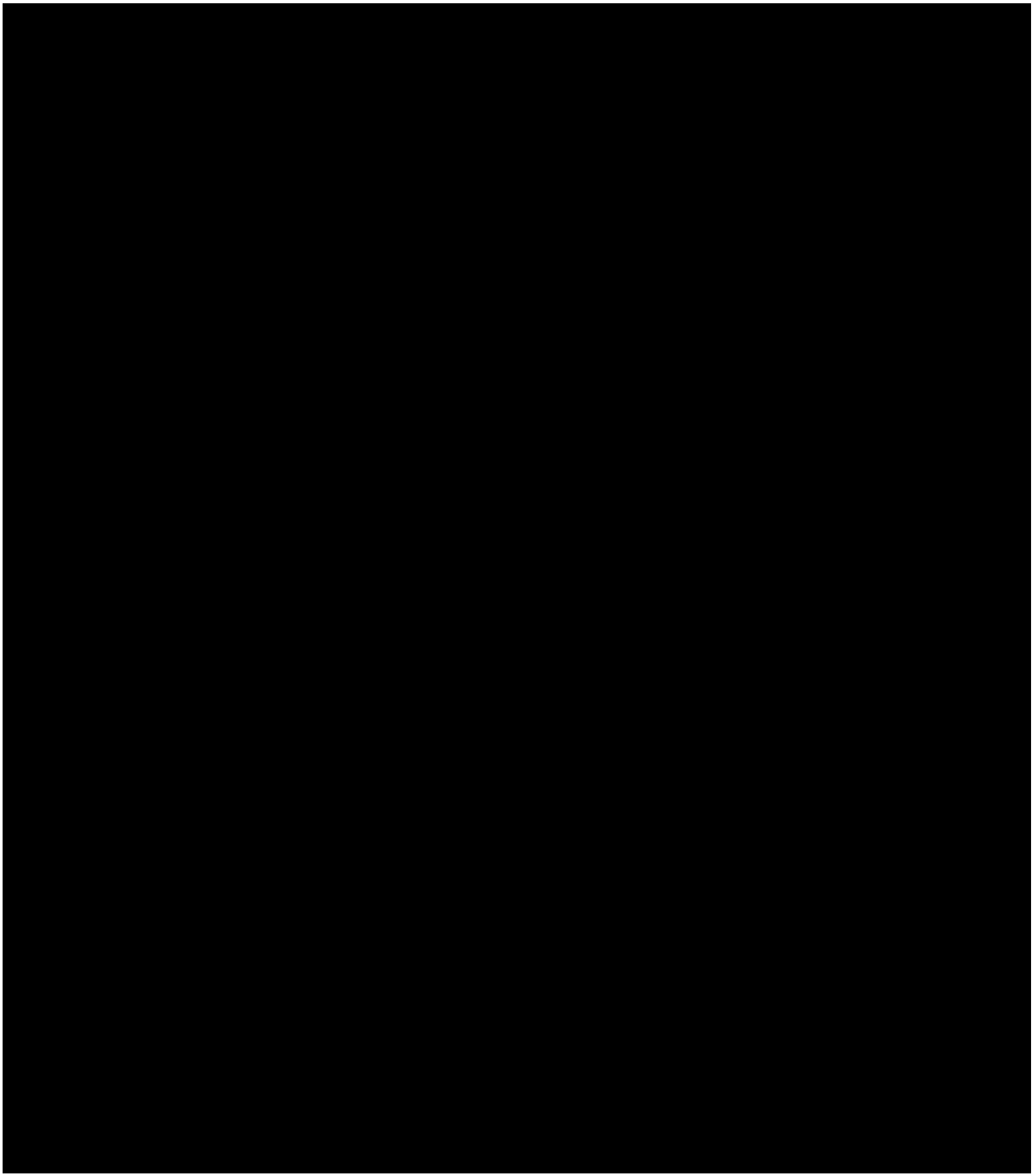
1. GC Calibration 1 (Method 18):	8:02 am – 8:45 am
3. Sample Point and Sample Line Inspections	9:00 am – 9:35 am
2. Sterilizer Chamber Vent Test # 1 (Simultaneous discharge from four sterilizers: S-1, S-4, S-8 & S-9)	9:57 am – 10:16 am
3. ARV Test Run # 1 (Header A & B): (Ten pallets of sterilized product across two aeration rooms)	11:25 am – 12:20 pm
4. ARV Test Run # 2 (Header A & B): (Ten pallets of sterilized product across two aeration rooms)	12:25 am – 1:20 pm
5. ARV Test Run # 3 (Header A & B): (Ten pallets of sterilized product across two aeration rooms)	1:25 pm – 2:20 pm
8. Sterilizer Chamber Vent Test # 2 (Chamber S-8):	2:36 pm – 2:52 pm
9. Sterilizer Chamber Vent Test # 3 (Chamber S-9):	2:58 pm – 3:14 pm

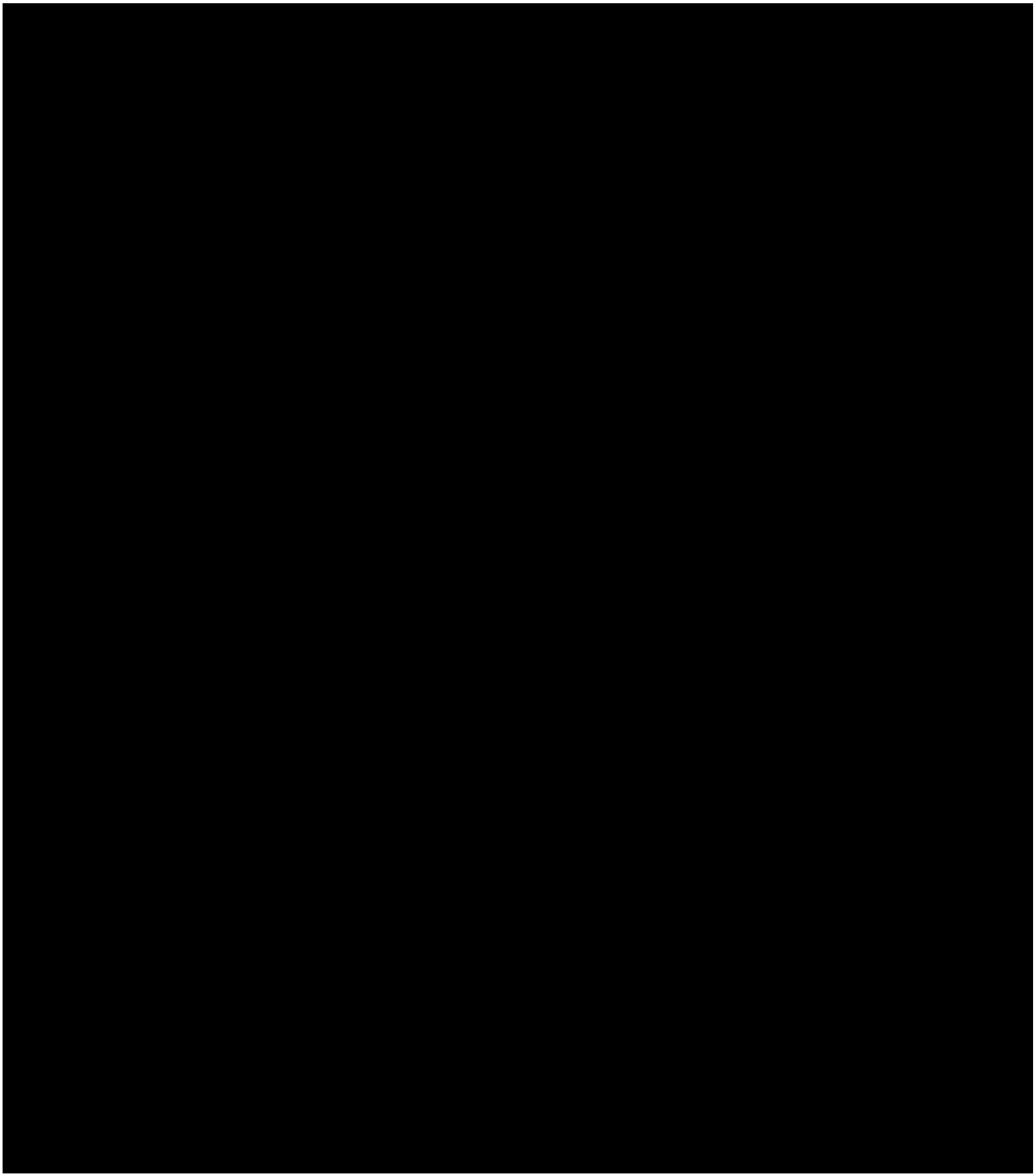
Efficiency Summary

SCV Test #1: 99.98%
SCV Test #2: 99.99%
SCV Test #3: 99.89%
Average Efficiency: **99.95%**

ARV Efficiency: **99.86%**

Compliant with Permit Conditions? **Yes**





APPENDIX F

CALBRATION PROCEDURES/DATA

[redacted]

ETHYLENE OXIDE SOURCE TEST/CALIBRATION DATA

Client: Cook Medical

Source Tested: AAT Safe Cell System Date: 7/27/18

PRE CALIBRATION

	Calibration Gas Conc. (ppmv)	1.10 ppm EtO	10.1 ppm EtO	100 ppm EtO	1000 ppm EtO	10080 ppm EtO			
Inlet (FID)	Area Counts #1	.445	4.14	40.2					
	Area Counts #2/3	.438 / .442	4.16 / 4.12	40.5 / 39.9					
	Average Area	.441	4.14	40.2					
	Audit Standard (48.8 ppmv) Result					49.6 ✓			
Outlet (PID)	Calibration Gas Conc. (ppmv)	1.10 ppm EtO	10.1 ppm EtO	100 ppm EtO					
	Area Counts #1	2.47	23.5	232					
	Area Counts #2/3	2.39 / 2.42	23.1 / 23.5	230 / 231					
	Average Area	2.42	23.4	231					
	Audit Standard (48.8 ppmv) Result					48.7 ✓			

	Run #1	Run #2	Run #3				
Exhaust start/stop:	957/1016	1436/1452	1458/1514	P_{bar}:	29.20	EtO Usage (lbs/yr):	—
Aeration start/stop:	1125/1225	1225/1325	1325/1425	%H_2O:	3	Cycles Per Week:	—

POST CALIBRATION

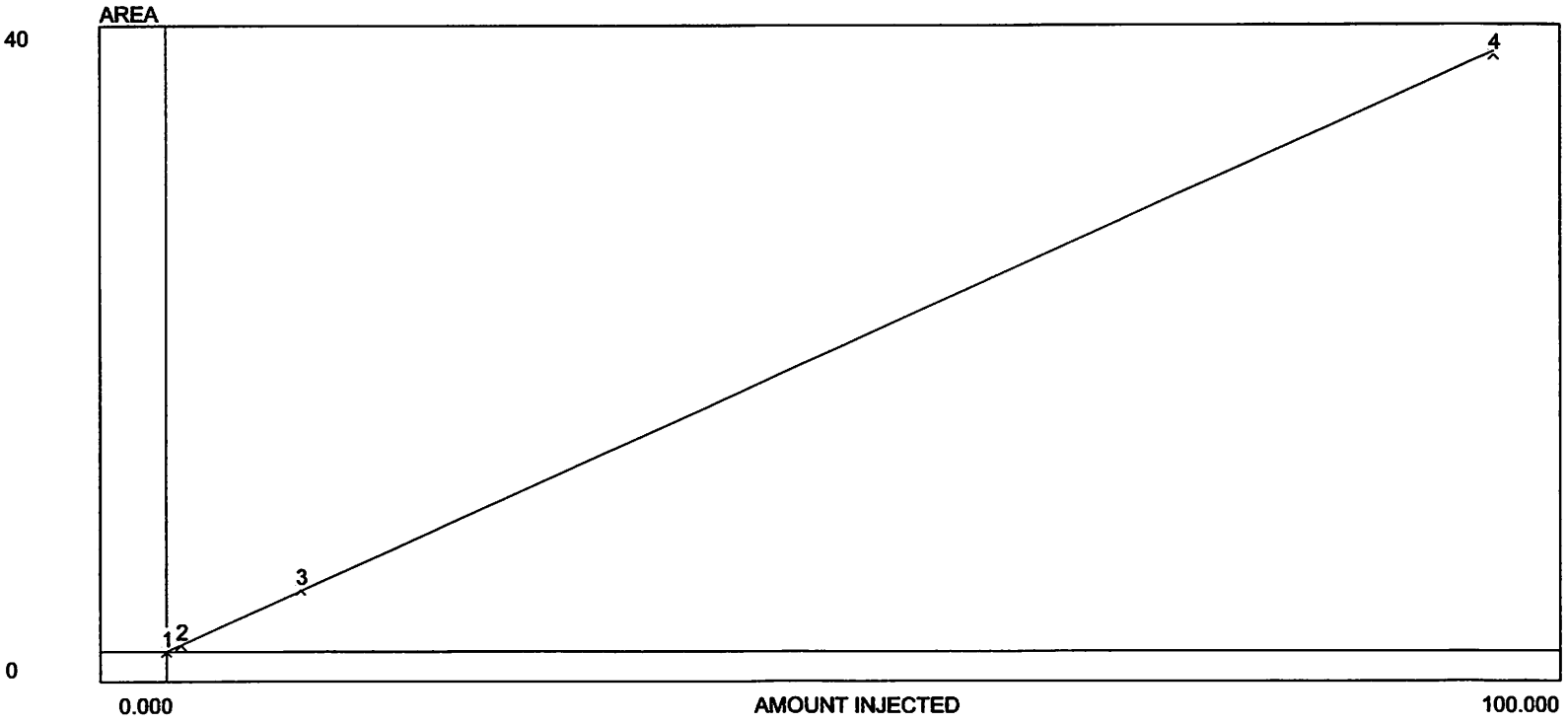
	Calibration Gas Conc. (ppmv)	1.10 ppm EtO	10.1 ppm EtO	100 ppm EtO	1000 ppm EtO	10080 ppm EtO			
Inlet (FID)	Area Counts #1								
	Area Counts #2		✓						
	Average Area								
	Audit Standard (48.8 ppmv) Result					48.3 ✓			
Outlet (PID)	Calibration Gas Conc. (ppmv)	1.10 ppm EtO	10.1 ppm EtO	100 ppm EtO					
	Area Counts #1								
	Area Counts #2		✓						
	Average Area								
	Audit Standard (48.8 ppmv) Result					48.4 ✓			

ECSi

Component file: eto1-100.cpt

Peak	Name	Start	End	Calibration	Int.Std	Units
1	Dead Vol / Air	0.000	0.300		0.000	
2	Ambient H2O	0.300	0.450		0.000	
3	Ethylene Oxide	0.450	0.540	C:\peak359\1Cool0.000.cappm		
4	Acetaldehyde	0.540	0.800		0.000	
5	CO2	0.800	1.000		0.000	

Calibration file: C:\peak359\1Cook2018.cal



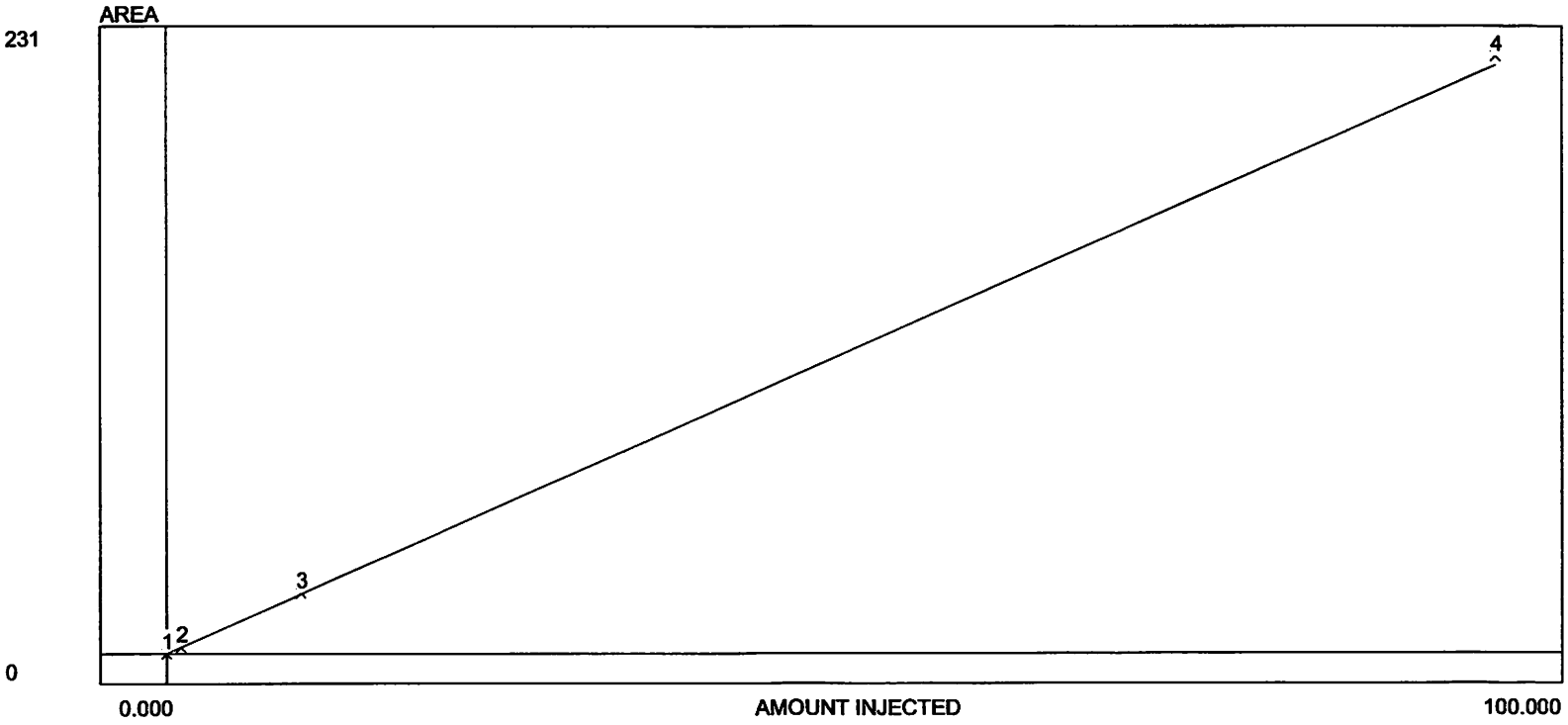
Avg slope of curve: 0.40
Y-axis intercept: 0.00
Linearity: 1.00
Number of levels: 4
SD/rel SD of CF's: 0.2/66.7
Y=0.4043X
r2: 1.0000
Last calibrated: Fri Jul 27 08:45:39 2018

Lvl.	Area/ht.	Amount	CF	Current	Previous #1	Previous #2
1	0.000	0.000	0.000	0.000	N/A	N/A
2	0.441	1.100	0.401	0.441	N/A	N/A
3	4.140	10.100	0.410	4.140	N/A	N/A
4	40.200	100.000	0.402	40.200	N/A	N/A

Component file: eto2-100.cpt

Peak	Name	Start	End	Calibration	Int.Std	Units
1	Dead Vol / Air	0.000	0.300		0.000	
2	Ambient H2O	0.300	0.450		0.000	
3	Ethylene Oxide	0.450	0.540	C:\peak359\2Cool0.000.cappm		
4	Acetaldehyde	0.540	0.800		0.000	
5	CO2	0.800	1.000		0.000	

Calibration file: C:\peak359\2Cook2018.cal



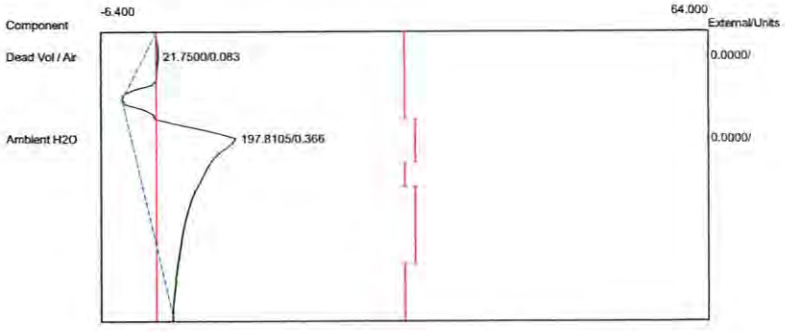
Avg slope of curve: 2.28
Y-axis intercept: 0.00
Linearity: 1.00
Number of levels: 4
SD/rel SD of CF's: 1.1/66.7
Y=2.2756X
r2: 1.0000
Last calibrated: Fri Jul 27 08:44:53 2018

Lvl.	Area/ht.	Amount	CF	Current	Previous #1	Previous #2
1	0.000	0.000	0.000	0.000	N/A	N/A
2	2.420	1.100	2.200	2.420	N/A	N/A
3	23.400	10.100	2.317	23.400	N/A	N/A
4	231.000	100.000	2.310	231.000	N/A	N/A

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 15:51:17
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-Amb.CHR (c:\peak359)
Sample: Ambient Background
Operator: D. Kremer

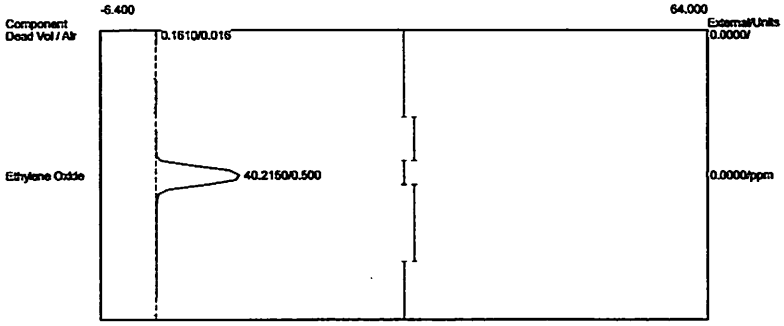
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.2860	0.0000	
Ambient H2O	0.416	1.5250	0.0000	
		3.8110	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 15:51:17
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-Amb.CHR (c:\peak359)
Sample: Ambient Background
Operator: D. Kremer



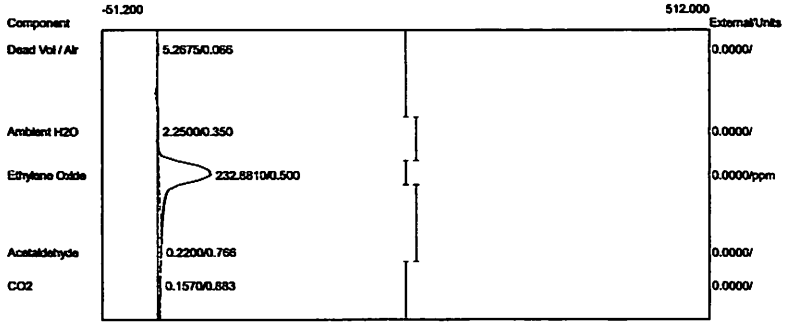
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.7500	0.0000	
Ambient H2O	0.366	197.8105	0.0000	
		219.5605	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:01:57
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C01.CHR (c:\peak359)
Sample: 100 ppm EtO std
Operator: D. Kremer



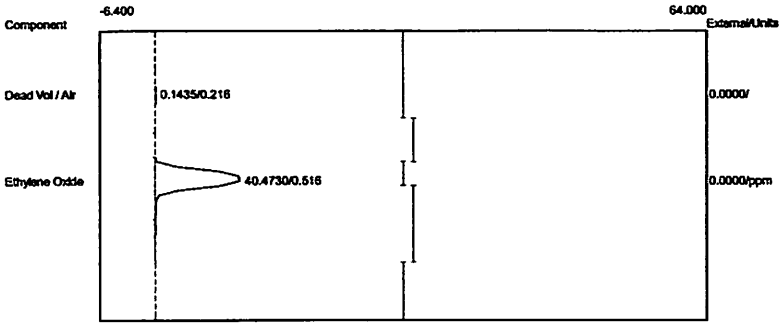
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	0.1610	0.0000	
Ethylene Oxide	0.500	40.2150	0.0000	ppm
		40.3760	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:01:57
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C01.CHR (c:\peak359)
Sample: 100 ppm EtO std
Operator: D. Kremer



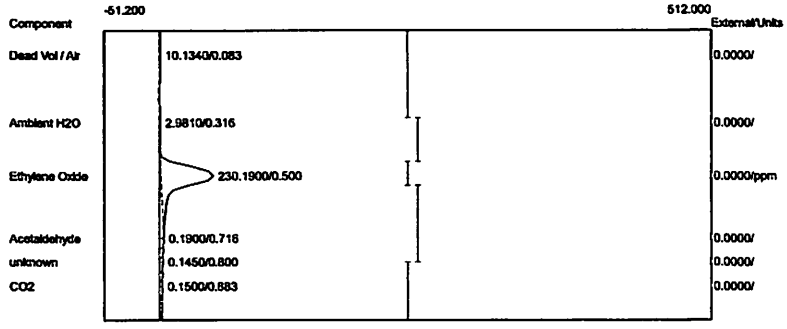
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	5.2675	0.0000	
Ambient H2O	0.350	2.2500	0.0000	
Ethylene Oxide	0.500	232.8810	0.0000	ppm
Acetaldehyde	0.766	0.2200	0.0000	
CO2	0.883	0.1570	0.0000	
		240.7755	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:03:51
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C02.CHR (c:\peak359)
Sample: 100 ppm EtO std
Operator: D. Kremer



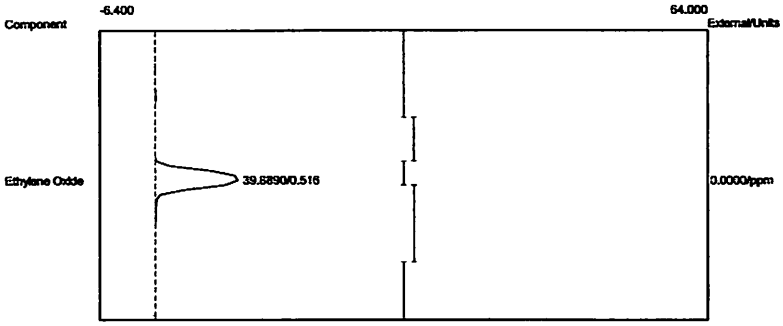
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	0.1435	0.0000	
Ethylene Oxide	0.516	40.4730	0.0000	ppm
		40.6165	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:03:51
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C02.CHR (c:\peak359)
Sample: 100 ppm EtO std
Operator: D. Kremer



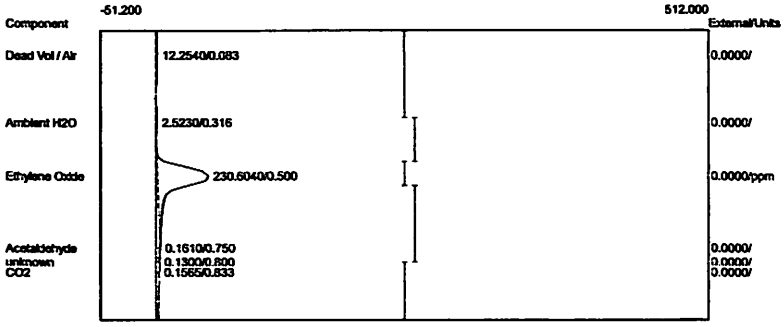
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	10.1340	0.0000	
Ambient H2O	0.316	2.9810	0.0000	
Ethylene Oxide	0.500	230.1900	0.0000	ppm
Acetaldehyde	0.716	0.1900	0.0000	
CO2	0.883	0.1500	0.0000	
		243.6450	0.0000	

Lab name: ECSI
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:05:42
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C03.CHR (c:\peak359)
Sample: 100 ppm EtO std
Operator: D. Kremer



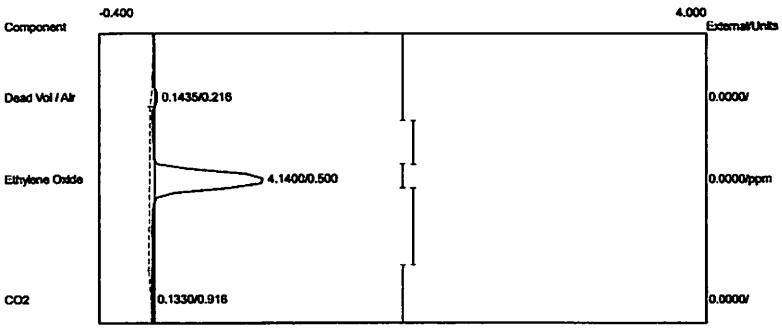
Component	Retention	Area	External	Units
Ethylene Oxide	0.516	39.8890	0.0000	ppm
		39.8890	0.0000	

Lab name: ECSI
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:05:42
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C03.CHR (c:\peak359)
Sample: 100 ppm EtO std
Operator: D. Kremer



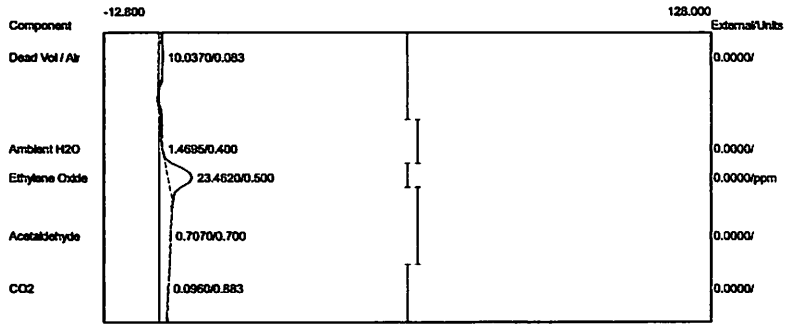
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	12.2540	0.0000	
Ambient H2O	0.316	2.5230	0.0000	
Ethylene Oxide	0.500	230.6040	0.0000	ppm
Acetaldehyde	0.750	0.1610	0.0000	
CO2	0.833	0.1565	0.0000	
		245.6985	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:10:30
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C04.CHR (c:\peak359)
Sample: 10.1 ppm EtO std
Operator: D. Kremer



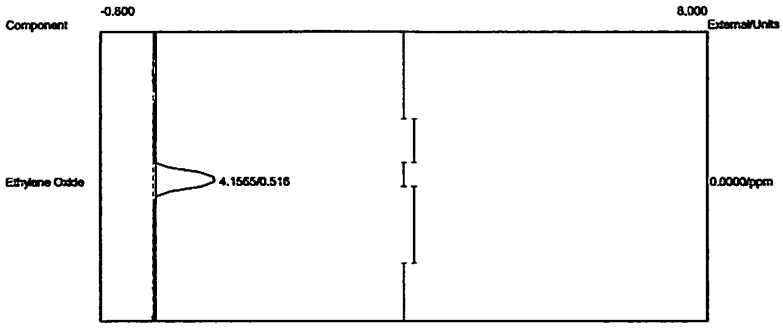
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	0.1435	0.0000	
Ethylene Oxide	0.500	4.1400	0.0000	ppm
CO2	0.916	0.1330	0.0000	
		4.4165	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:10:30
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C04.CHR (c:\peak359)
Sample: 10.1 ppm EtO std
Operator: D. Kremer



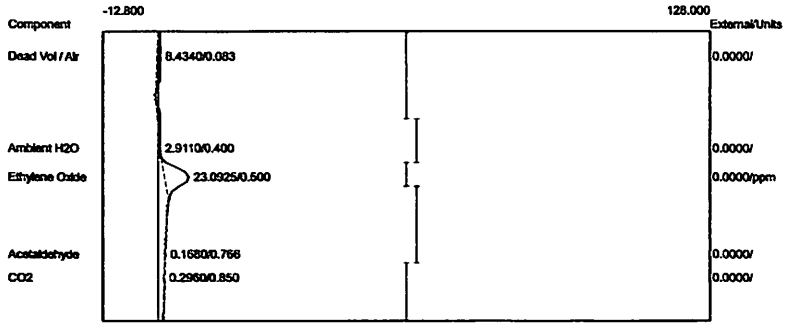
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	10.0370	0.0000	
Ambient H2O	0.400	1.4695	0.0000	
Ethylene Oxide	0.500	23.4620	0.0000	ppm
Acetaldehyde	0.700	0.7070	0.0000	
CO2	0.883	0.0960	0.0000	
		35.7715	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:18:11
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C05.CHR (c:\peak359)
Sample: 10.1 ppm EtO std
Operator: D. Kremer



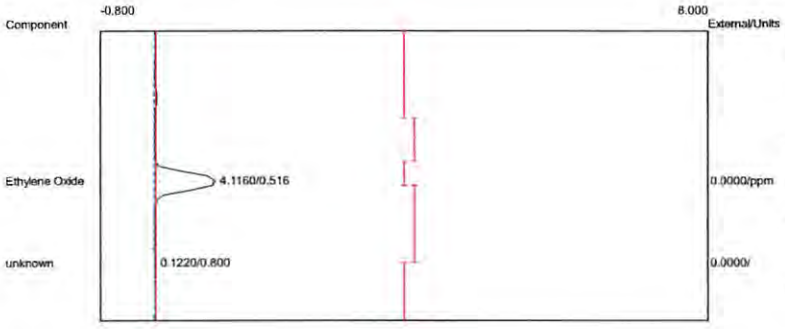
Component	Retention	Area	External	Units
Ethylene Oxide	0.516	4.1565	0.0000	ppm
		4.1565	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:18:11
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C05.CHR (c:\peak359)
Sample: 10.1 ppm EtO std
Operator: D. Kremer



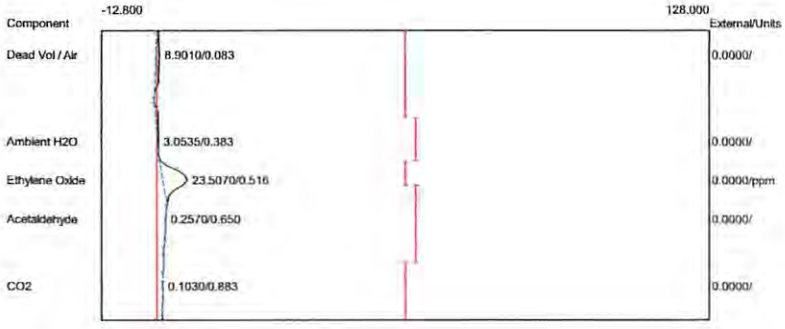
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	8.4340	0.0000	
Ambient H2O	0.400	2.9110	0.0000	
Ethylene Oxide	0.500	23.0925	0.0000	ppm
Acetaldehyde	0.766	0.1680	0.0000	
CO2	0.850	0.2960	0.0000	
		34.9015	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:23:15
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C06.CHR (c:\peak359)
Sample: 10.1 ppm EtO std
Operator: D. Kremer



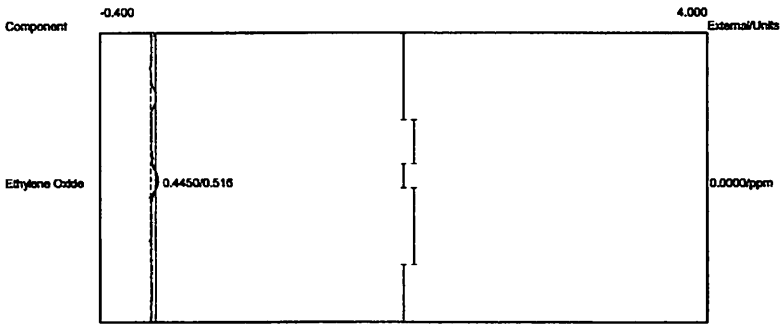
Component	Retention	Area	External	Units
Ethylene Oxide	0.516	4.1160	0.0000	ppm
		4.1160	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:23:15
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C06.CHR (c:\peak359)
Sample: 10.1 ppm EtO std
Operator: D. Kremer



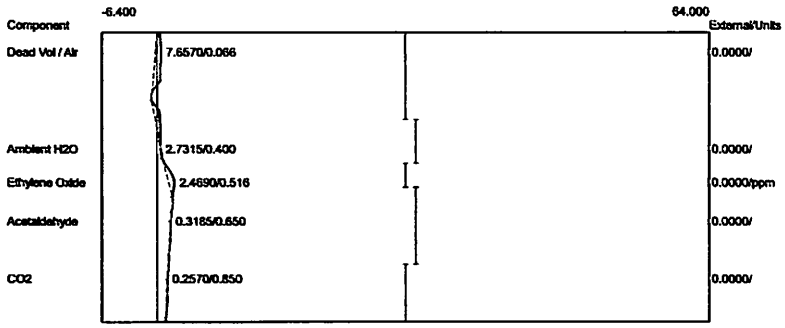
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	8.9010	0.0000	
Ambient H2O	0.383	3.0535	0.0000	
Ethylene Oxide	0.516	23.5070	0.0000	ppm
Acetaldehyde	0.650	0.2570	0.0000	
CO2	0.883	0.1030	0.0000	
		35.8215	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:27:44
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C07.CHR (c:\peak359)
Sample: 1.10 ppm EtO std
Operator: D. Kremer



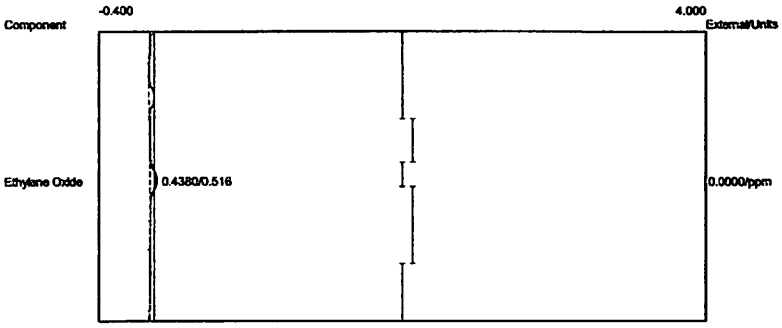
Component	Retention	Area	External	Units
Ethylene Oxide	0.516	0.4450	0.0000	ppm
		0.4450	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:27:44
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C07.CHR (c:\peak359)
Sample: 1.10 ppm EtO std
Operator: D. Kremer



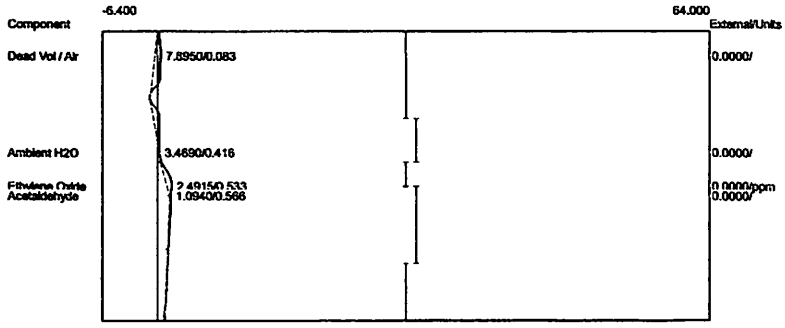
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	7.6570	0.0000	
Ambient H2O	0.400	2.7315	0.0000	
Ethylene Oxide	0.516	2.4690	0.0000	ppm
Acetaldehyde	0.650	0.3185	0.0000	
CO2	0.850	0.2570	0.0000	
		13.4330	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:31:51
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C08.CHR (c:\peak359)
Sample: 1.10 ppm EtO std
Operator: D. Kremer



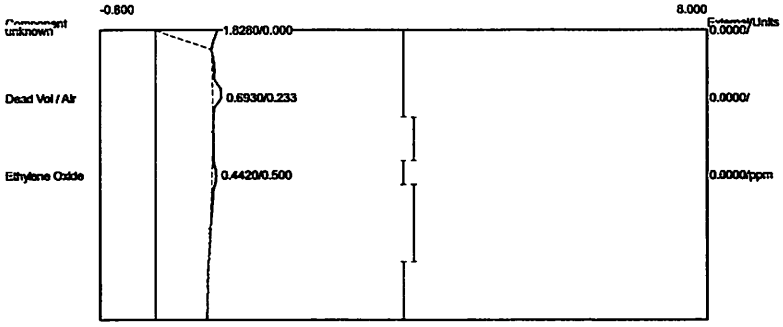
Component	Retention	Area	External	Units
Ethylene Oxide	0.516	0.4380	0.0000	ppm
		0.4380	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:31:51
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C08.CHR (c:\peak359)
Sample: 1.10 ppm EtO std
Operator: D. Kremer



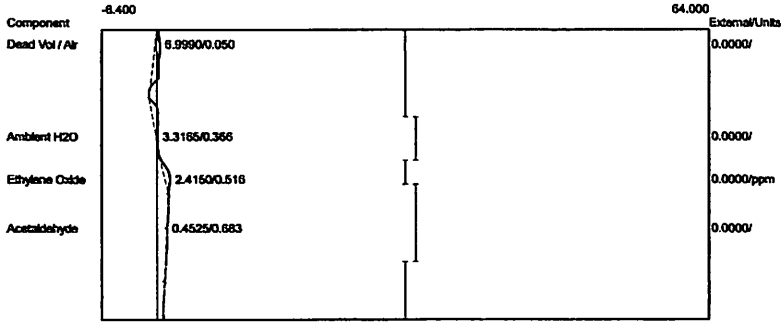
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	7.8950	0.0000	
Ambient H2O	0.416	3.4690	0.0000	
Ethylene Oxide	0.533	2.4915	0.0000	ppm
Acetaldehyde	0.566	1.0940	0.0000	
		14.9495	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:36:34
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C09.CHR (c:\peak359)
Sample: 1.10 ppm EtO std
Operator: D. Kremer



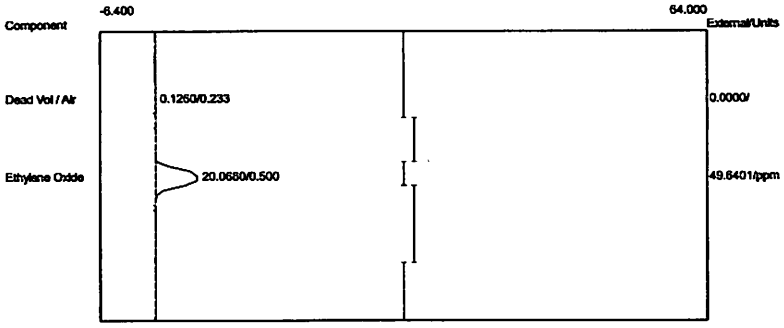
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	0.6930	0.0000	
Ethylene Oxide	0.500	0.4420	0.0000	ppm
		1.1350	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:36:34
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C09.CHR (c:\peak359)
Sample: 1.10 ppm EtO std
Operator: D. Kremer



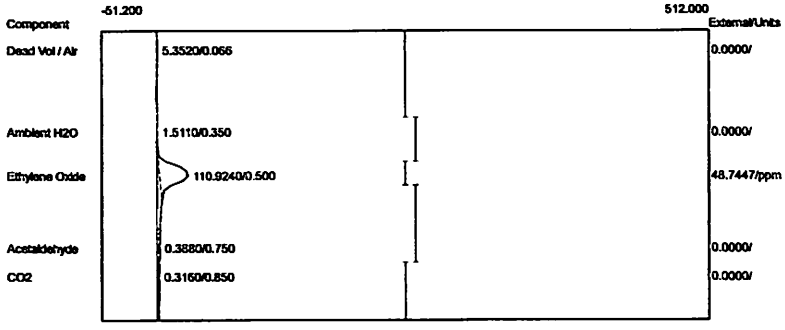
Component	Retention	Area	External	Units
Dead Vol / Air	0.050	6.9990	0.0000	
Ambient H2O	0.366	3.3165	0.0000	
Ethylene Oxide	0.516	2.4150	0.0000	ppm
Acetaldehyde	0.683	0.4525	0.0000	
		13.1830	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:44:15
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C10.CHR (c:\peak359)
Sample: 48.8 ppm EtO std
Operator: D. Kremer



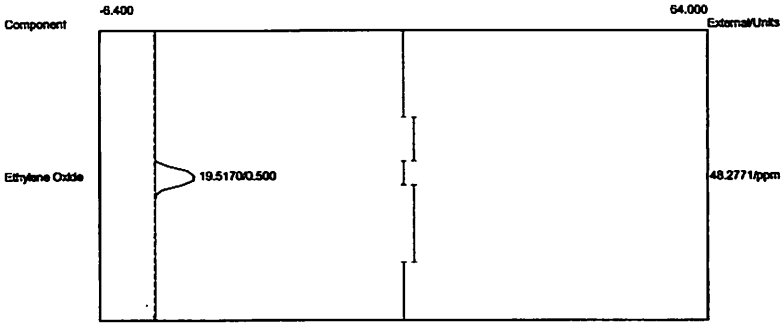
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	0.1260	0.0000	
Ethylene Oxide	0.500	20.0680	49.6401	ppm
		20.1940	49.6401	

Lab name: ECSi
Client: Cook Medical
Client ID: PreCal
Analysis date: 07/27/2018 08:44:15
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C10.CHR (c:\peak359)
Sample: 48.8 ppm EtO std
Operator: D. Kremer



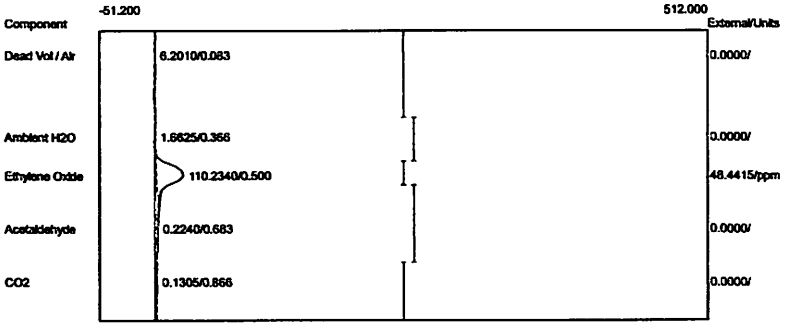
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	5.3520	0.0000	
Ambient H2O	0.350	1.5110	0.0000	
Ethylene Oxide	0.500	110.9240	48.7447	ppm
Acetaldehyde	0.750	0.3880	0.0000	
CO2	0.850	0.3160	0.0000	
		118.4910	48.7447	

Lab name: ECSi
Client: Cook Medical
Client ID: ~~PreCal~~ Postcal
Analysis date: 07/27/2018 15:48:06
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-C11.CHR (c:\peak359)
Sample: 48.8 ppm EtO std
Operator: D. Kremer



Component	Retention	Area	External	Units
Ethylene Oxide	0.500	19.5170	48.2771	ppm
		19.5170	48.2771	

Lab name: ECSi
Client: Cook Medical
Client ID: ~~PreCal~~ Postcal
Analysis date: 07/27/2018 15:48:06
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-C11.CHR (c:\peak359)
Sample: 48.8 ppm EtO std
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.083	6.2010	0.0000	
Ambient H2O	0.366	1.6625	0.0000	
Ethylene Oxide	0.500	110.2340	48.4415	ppm
Acetaldehyde	0.683	0.2240	0.0000	
CO2	0.866	0.1305	0.0000	
		118.4520	48.4415	

METHOD 18 - MEASUREMENT OF GASEOUS ORGANIC COMPOUND EMISSIONS BY GAS CHROMATOGRAPHY

NOTE: This method is not inclusive with respect to specifications (e.g., equipment and supplies) and procedures (e.g., sampling and analytical) essential to its performance. Some material is incorporated by reference from other methods in this part. Therefore, to obtain reliable results, persons using this method should have a thorough knowledge of at least the following additional test methods: Method 1, Method 2, Method 3.

NOTE: This method should not be attempted by persons unfamiliar with the performance characteristics of gas chromatography, nor by those persons who are unfamiliar with source sampling. Particular care should be exercised in the area of safety concerning choice of equipment and operation in potentially explosive atmospheres.

1.0 Scope and Application.

1.1 Analyte. Total gaseous organic compounds.

1.2 Applicability.

1.2.1 This method is designed to measure gaseous organics emitted from an industrial source. While designed for ppm level sources, some detectors are quite capable of detecting compounds at ambient levels, e.g., ECD, ELCD, and helium ionization detectors. Some other types of detectors are evolving such that the sensitivity and applicability may well be in the ppb range in only a few years.

1.2.2 This method will not determine compounds that (1) are polymeric (high molecular weight), (2) can polymerize before analysis, or (3) have very low vapor pressures at stack or instrument conditions.

1.3 Range. The lower range of this method is determined by the sampling system; adsorbents may be used to concentrate the sample, thus lowering the limit of detection below the 1 part per million (ppm) typically achievable with direct interface or bag sampling. The upper limit is governed by GC detector saturation or column overloading; the upper range can be extended by dilution of sample with an inert gas or by using smaller volume gas sampling loops. The upper limit can also be governed by condensation of higher boiling compounds.

1.4 Sensitivity. The sensitivity limit for a compound is defined as the minimum detectable concentration of that compound, or the concentration that produces a signal-to-noise ratio of three to one. The minimum detectable concentration is determined during the presurvey calibration for each compound.

2.0 Summary of Method.

The major organic components of a gas mixture are separated by gas chromatography (GC) and individually quantified by flame ionization, photoionization, electron capture, or other appropriate detection principles. The retention times of each separated component are compared with those of known compounds under identical conditions. Therefore, the analyst confirms the identity and approximate concentrations of the organic emission components beforehand. With this information, the analyst then prepares or purchases commercially available standard mixtures to calibrate the GC under conditions identical to those of the samples. The analyst also determines the need for sample dilution to avoid detector saturation, gas stream filtration to eliminate particulate matter, and prevention of moisture condensation.

3.0 Definitions. [Reserved]

4.0 Interferences.

4.1 Resolution interferences that may occur can be eliminated by appropriate GC column and detector choice or by shifting the retention times through changes in the column flow rate and the use of temperature programming.

4.2 The analytical system is demonstrated to be essentially free from contaminants by periodically analyzing blanks that consist of hydrocarbon-free air or nitrogen.

4.3 Sample cross-contamination that occurs when high-level and low-level samples or standards are analyzed alternately is best dealt with by thorough purging of the GC sample loop between samples.

4.4 To assure consistent detector response, calibration gases are contained in dry air. To adjust gaseous organic concentrations when water vapor is present in the sample, water vapor concentrations are determined for those samples, and a correction factor is applied.

4.5 The gas chromatograph run time must be sufficient to clear all eluting peaks from the column before proceeding to the next run (in order to prevent sample carryover).

5.0 Safety.

5.1 Disclaimer. This method may involve hazardous materials, operations, and equipment. This test method may not address all of the safety problems associated with its use. It is the responsibility of the user of this test method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to performing this test method. The analyzer users manual should be consulted for specific precautions to be taken with regard to the analytical procedure.

6.0 Equipment and Supplies.

6.1 Equipment needed for the presurvey sampling procedure can be found in Section 16.1.1.

6.2 Equipment needed for the integrated bag sampling and analysis procedure can be found in Section 8.2.1.1.1.
6.3 Equipment needed for direct interface sampling and analysis can be found in Section 8.2.2.1.
6.4 Equipment needed for the dilution interface sampling and analysis can be found in Section 8.2.3.1.
6.5 Equipment needed for adsorbent tube sampling and analysis can be found in Section 8.2.4.1.
7.0 Reagents and Standards.
7.1 Reagents needed for the presurvey sampling procedure can be found in Section 16.1.2.
7.2 Quality Assurance Audit Samples. When making compliance determinations, and upon availability, an audit sample may be obtained from the appropriate EPA Regional Office or from the responsible enforcement authority.
NOTE: The responsible enforcement autority should be notified at least 30 days prior to the test date to allow sufficient time for sample delivery.
8.0 Sample Collection, Preservation, Storage, and Transport.
8.2 Final Sampling and Analysis Procedure. Considering safety (flame hazards) and the source conditions, select an appropriate sampling and analysis procedure (Section 8.2.1, 8.2.2, 8.2.3 or 8.2.4). In situations where a hydrogen flame is a hazard and no intrinsically safe GC is suitable, use the flexible bag collection technique or an adsorption technique.
8.2.1 Integrated Bag Sampling and Analysis.
8.2.1.1 Evacuated Container Sampling Procedure. In this procedure, the bags are filled by evacuating the rigid air-tight container holding the bags. Use a field sample data sheet as shown in Figure 18-10. Collect triplicate samples from each sample location.
8.2.1.1.1 Apparatus.
8.2.1.1.1.1 Probe. Stainless steel, Pyrex glass, or Teflon tubing probe, according to the duct temperature, with Teflon tubing of sufficient length to connect to the sample bag. Use stainless steel or Teflon unions to connect probe and sample line.
8.2.1.1.1.2 Quick Connects. Male (2) and female (2) of stainless steel construction.
8.2.1.1.1.3 Needle Valve. To control gas flow.
8.2.1.1.1.4 Pump. Leakless Teflon-coated diaphragm-type pump or equivalent. To deliver at least 1 liter/min.
8.2.1.1.1.5 Charcoal Adsorption Tube. Tube filled with activated charcoal, with glass wool plugs at each end, to adsorb organic vapors.
8.2.1.1.1.6 Flowmeter. O to 500-ml flow range; with manufacturer's calibration curve.
8.2.1.1.2 Sampling Procedure. To obtain a sample, assemble the sample train as shown in Figure 18-9. Leak- check both the bag and the container. Connect the vacuum line from the needle valve to the Teflon sample line from the probe. Place the end of the probe at the centroid of the stack or at a point no closer to the walls than 1 m, and start the pump. Set the flow rate so that the final volume of the sample is approximately 80 percent of the bag capacity. After allowing sufficient time to purge the line several times, connect the vacuum line to the bag, and evacuate until the rotameter indicates no flow. Then position the sample and vacuum lines for sampling, and begin the actual sampling, keeping the rate proportional to the stack velocity. As a precaution, direct the gas exiting the rotameter away from sampling personnel. At the end of the sample period, shut off the pump, disconnect the sample line from the bag, and disconnect the vacuum line from the bag container. Record the source temperature, barometric pressure, ambient temperature, sampling flow rate, and initial and final sampling time on the data sheet shown in Figure 18-10. Protect the Tedlar bag and its container from sunlight. Record the time lapsed between sample collection and analysis, and then conduct the recovery procedure in Section 8.4.2.
8.2.1.2 Direct Pump Sampling Procedure. Follow 8.2.1.1, except place the pump and needle valve between the probe and the bag. Use a pump and needle valve constructed of inert material not affected by the stack gas. Leak-check the system, and then purge with stack gas before connecting to the previously evacuated bag.
8.2.1.3 Explosion Risk Area Bag Sampling Procedure. Follow 8.2.1.1 except replace the pump with another evacuated can (see Figure 18-9a). Use this method whenever there is a possibility of an explosion due to pumps, heated probes, or other flame producing equipment.
8.2.1.4 Other Modified Bag Sampling Procedures. In the event that condensation is observed in the bag while collecting the sample and a direct interface system cannot be used, heat the bag during collection, and maintain it at a suitably elevated temperature during all subsequent operations. (NOTE: Take care to leak-check the system prior to the dilutions so as not to create a potentially explosive atmosphere.) As an alternative, collect the sample gas, and simultaneously dilute it in the Tedlar bag.
8.2.1.4.1 First Alternative Procedure. Heat the box containing the sample bag to 120 °C (± 5 °C). Then transport the bag as rapidly as possible to the analytical area while maintaining the heating, or cover the box with an insulating blanket. In the analytical area, keep the box heated to 120 °C (±5 °C) until analysis. Be sure that the method of heating the box and the control for the heating circuit are compatible with the safety restrictions required in each area.
8.2.1.4.2 Second Alternative Procedure. Prefill the Tedlar bag with a known quantity of inert gas. Meter the inert gas into the bag according to the procedure for the preparation of gas concentration standards of volatile liquid materials (Section

10.1.2.2), but eliminate the midget impinger section. Take the partly filled bag to the source, and meter the source gas into the bag through heated sampling lines and a heated flowmeter, or Teflon positive displacement pump. Verify the dilution factors before sampling each bag through dilution and analysis of gases of known concentration.

8.2.1.5 Analysis of Bag Samples.

8.2.1.5.1 Apparatus. Same as Section 8.1. A minimum of three gas standards are required.

8.2.1.5.2 Procedure.

8.2.1.5.2.1 Establish proper GC operating conditions as described in Section 10.2, and record all data listed in Figure 18-7. Prepare the GC so that gas can be drawn through the sample valve. Flush the sample loop with calibration gas mixture, and activate the valve (sample pressure at the inlet to the GC introduction valve should be similar during calibration as during actual sample analysis). Obtain at least three chromatograms for the mixture. The results are acceptable when the peak areas for the three injections agree to within 5 percent of their average. If they do not agree, run additional samples or correct the analytical techniques until this requirement is met. Then analyze the other two calibration mixtures in the same manner. Prepare a calibration curve as described in Section 10.2.

8.2.1.5.2.2 Analyze the two field audit samples as described in Section 9.2 by connecting each Tedlar bag containing an audit gas mixture to the sampling valve. Calculate the results; record and report the data to the audit supervisor.

8.2.1.5.2.3 Analyze the three source gas samples by connecting each bag to the sampling valve with a piece of Teflon tubing identified with that bag. Analyze each bag sample three times. Record the data in Figure 18-11. If certain items do not apply, use the notation "N.A." If the bag has been maintained at an elevated temperature as described in Section 8.2.1.4, determine the stack gas water content by Method 4. After all samples have been analyzed, repeat the analysis of the mid-level calibration gas for each compound. Compare the average response factor of the pre- and post-test analysis for each compound. If they differ by > 5 percent, analyze the other calibration gas levels for that compound, and prepare a calibration curve using all the pre- and post-test calibration gas mixture values. If the two response factor averages (pre- and post-test) differ by less than 5 percent from their mean value, the tester has the option of using only the pre-test calibration curve to generate the concentration values.

8.2.1.6 Determination of Bag Water Vapor Content. Measure the ambient temperature and barometric pressure near the bag. From a water saturation vapor pressure table, determine and record the water vapor content of the bag as a decimal figure. (Assume the relative humidity to be 100 percent unless a lesser value is known.) If the bag has been maintained at an elevated temperature as described in Section 8.2.1.4, determine the stack gas water content by Method 4.

8.2.1.7 Audit Gas Analysis. Immediately prior to the analysis of the stack gas samples, perform audit analyses as described in Section 9.2.

8.2.1.8 Emission Calculations. From the calibration curve described in Section 8.2.1.5, select the value of C_s that corresponds to the peak area. Calculate the concentration C_c in ppm, dry basis, of each organic in the sample using Equation 18-5 in Section 12.6.

8.2.2 Direct Interface Sampling and Analysis Procedure. The direct interface procedure can be used provided that the moisture content of the gas does not interfere with the analysis procedure, the physical requirements of the equipment can be met at the site, and the source gas concentration falls within the linear range of the detector. Adhere to all safety requirements with this method.

8.2.2.1 Apparatus.

8.2.2.1.1 Probe. Constructed of stainless steel, Pyrex glass, or Teflon tubing as dictated by duct temperature and reactivity of target compounds. A filter or glass wool plug may be needed if particulate is present in the stack gas. If necessary, heat the probe with heating tape or a special heating unit capable of maintaining a temperature greater than 110°C.

8.2.2.1.2 Sample Lines. 6.4-mm OD (or other diameter as needed) Teflon lines, heat-traced to prevent condensation of material (greater than 110°C).

8.2.2.1.3 Quick Connects. To connect sample line to gas sampling valve on GC instrument and to pump unit used to withdraw source gas. Use a quick connect or equivalent on the cylinder or bag containing calibration gas to allow connection of the calibration gas to the gas sampling valve. 8.2.2.1.4 Thermocouple Readout Device. Potentiometer or digital thermometer, to measure source temperature and probe temperature.

8.2.2.1.5 Heated Gas Sampling Valve. Of two-position, six-port design, to allow sample loop to be purged with source gas or to direct source gas into the GC instrument.

8.2.2.1.6 Needle Valve. To control gas sampling rate from the source.

8.2.2.1.7 Pump. Leakless Teflon-coated diaphragm-type pump or equivalent, capable of at least 1 liter/minute sampling rate.

8.2.2.1.8 Flowmeter. Of suitable range to measure sampling rate.
8.2.2.1.9 Charcoal Adsorber. To adsorb organic vapor vented from the source to prevent exposure of personnel to source gas.
8.2.2.1.10 Gas Cylinders. Carrier gas, oxygen and fuel as needed to run GC and detector.
8.2.2.1.11 Gas Chromatograph. Capable of being moved into the field, with detector, heated gas sampling valve, column required to complete separation of desired components, and option for temperature programming.
8.2.2.1.12 Recorder/Integrator. To record results.

8.2.2.2 Procedure. Calibrate the GC using the procedures in Section 8.2.1.5.2.1. To obtain a stack gas sample, assemble the sampling system as shown in Figure 18-12. Make sure all connections are tight. Turn on the probe and sample line heaters. As the temperature of the probe and heated line approaches the target temperature as indicated on the thermocouple readout device, control the heating to maintain a temperature greater than 110°C. Conduct a 3-point calibration of the GC by analyzing each gas mixture in triplicate. Generate a calibration curve. Place the inlet of the probe at the centroid of the duct, or at a point no closer to the walls than 1 m, and draw source gas into the probe, heated line, and sample loop. After thorough flushing, analyze the stack gas sample using the same conditions as for the calibration gas mixture. For each run, sample, analyze, and record five consecutive samples. A test consists of three runs (five samples per run times three runs, for a total of fifteen samples). After all samples have been analyzed, repeat the analysis of the mid-level calibration gas for each compound. For each calibration standard, compare the pre- and post-test average response factors (RF) for each compound. If the two calibration RF values (pre and post-analysis) differ by more than 5 percent from their mean value, then analyze the other calibration gas levels for that compound and determine the stack gas sample concentrations by comparison to both calibration curves (this is done by preparing a calibration curve using all the pre and post-test calibration gas mixture values). If the two calibration RF values differ by less than 5 percent from their mean value, the tester has the option of using only the pre-test calibration curve to generate the concentration values. Record this calibration data and the other required data on the data sheet shown in Figure 18-11, deleting the dilution gas information.
(NOTE: Take care to draw all samples, calibration mixtures, and audits through the sample loop at the same pressure.)
8.2.2.3 Determination of Stack Gas Moisture Content. Use Method 4 to measure the stack gas moisture content.
8.2.2.4 Quality Assurance. Same as Section 8.2.1.7. Introduce the audit gases in the sample line immediately following the probe.
8.2.2.5 Emission Calculations. Same as Section 8.2.1.8.
8.2.3 Dilution Interface Sampling and Analysis Procedure. Source samples that contain a high concentration of organic materials may require dilution prior to analysis to prevent saturating the GC detector. The apparatus required for this direct interface procedure is basically the same as that described in the Section 8.2.2, except a dilution system is added between the heated sample line and the gas sampling valve. The apparatus is arranged so that either a 10:1 or 100:1 dilution of the source gas can be directed to the chromatograph. A pump of larger capacity is also required, and this pump must be heated and placed in the system between the sample line and the dilution apparatus.
8.2.3.1 Apparatus. The equipment required in addition to that specified for the direct interface system is as follows:
8.2.3.1.1 Sample Pump. Leakless Teflon-coated diaphragm-type that can withstand being heated to 120°C and deliver 1.5 liters/minute.
8.2.3.1.2 Dilution Pumps. Two Model A-150 Komhyr Teflon positive displacement type delivering 150 cc/minute, or equivalent. As an option, calibrated flowmeters can be used in conjunction with Teflon-coated diaphragm pumps.
8.2.3.1.3 Valves. Two Teflon three-way valves, suitable for connecting to Teflon tubing.
8.2.3.1.4 Flowmeters. Two, for measurement of diluent gas.
8.2.3.1.5 Diluent Gas with Cylinders and Regulators. Gas can be nitrogen or clean dry air, depending on the nature of the source gases.
8.2.3.1.6 Heated Box. Suitable for being heated to 120°C, to contain the three pumps, three-way valves, and associated connections. The box should be equipped with quick connect fittings to facilitate connection of: (1) the heated sample line from the probe, (2) the gas sampling valve, (3) the calibration gas mixtures, and (4) diluent gas lines. A schematic diagram of the components and connections is shown in Figure 18-13. The heated box shown in Figure 18-13 is designed to receive a heated line from the probe. An optional design is to build a probe unit that attaches directly to the heated box. In this way, the heated box contains the controls for the probe heaters, or, if the box is placed against the duct being sampled, it may be possible to eliminate the probe heaters. In either case, a heated Teflon line is used to connect the heated box to the gas

sampling valve on the chromatograph.
NOTE: Care must be taken to leak-check the system prior to the dilutions so as not to create a potentially explosive atmosphere.
8.2.3.2 Procedure.
8.2.3.2.1 Assemble the apparatus by connecting the heated box, shown in Figure 18-13, between the heated sample line from the probe and the gas sampling valve on the chromatograph. Vent the source gas from the gas sampling valve directly to the charcoal filter, eliminating the pump and rotameter. Heat the sample probe, sample line, and heated box. Insert the probe and source thermocouple at the centroid of the duct, or to a point no closer to the walls than 1 m. Measure the source temperature, and adjust all heating units to a temperature 0 to 3°C above this temperature. If this temperature is above the safe operating temperature of the Teflon components, adjust the heating to maintain a temperature high enough to prevent condensation of water and organic compounds (greater than 110°C). Calibrate the GC through the dilution system by following the procedures in Section 8.2.1.5.2.1. Determine the concentration of the diluted calibration gas using the dilution factor and the certified concentration of the calibration gas. Record the pertinent data on the data sheet shown in Figure 18-11.
8.2.3.2.2 Once the dilution system and GC operations are satisfactory, proceed with the analysis of source gas, maintaining the same dilution settings as used for the standards.
8.2.3.2.3 Analyze the audit samples using either the dilution system, or directly connect to the gas sampling valve as required. Record all data and report the results to the audit supervisor.
8.2.3.3 Determination of Stack Gas Moisture Content. Same as Section 8.2.2.3.
8.2.3.4 Quality Assurance. Same as Section 8.2.2.4.
8.2.3.5 Emission Calculations. Same as section 8.2.2.5, with the dilution factor applied.
8.2.4 Adsorption Tube Procedure. Any commercially available adsorbent is allowed for the purposes of this method, as long as the recovery study criteria in Section 8.4.3 are met. Help in choosing the adsorbent may be found by calling the distributor, or the tester may refer to National Institute for Occupational Safety and Health (NIOSH) methods for the particular organics to be sampled. For some adsorbents, the principal interferent will be water vapor. If water vapor is thought to be a problem, the tester may place a midget impinger in an ice bath before the adsorbent tubes. If this option is chosen, the water catch in the midget impinger shall be analyzed for the target compounds. Also, the spike for the recovery study (in Section 8.4.3) shall be conducted in both the midget impinger and the adsorbent tubes. The combined recovery (add the recovered amount in the impinger and the adsorbent tubes to calculate R) shall then meet the criteria in Section 8.4.3.
NOTE: Post-test leak-checks are not allowed for this technique since this can result in sample contamination.
8.2.4.1 Additional Apparatus. The following items (or equivalent) are suggested.
8.2.4.1.1 Probe. Borosilicate glass or stainless steel, approximately 6-mm ID, with a heating system if water condensation is a problem, and a filter (either in-stack or out-of-stack, heated to stack temperature) to remove particulate matter. In most instances, a plug of glass wool is a satisfactory filter.
8.2.4.1.2 Flexible Tubing. To connect probe to adsorption tubes. Use a material that exhibits minimal sample adsorption.
8.2.4.1.3 Leakless Sample Pump. Flow controlled, constant rate pump, with a set of limiting (sonic) orifices.
8.2.4.1.4 Bubble-Tube Flowmeter. Volume accuracy within 1 percent, to calibrate pump.
8.2.4.1.5 Stopwatch. To time sampling and pump rate calibration.
8.2.4.1.6 Adsorption Tubes. Precleaned adsorbent, with mass of adsorbent to be determined by calculating breakthrough volume and expected concentration in the stack.
8.2.4.1.7 Barometer. Accurate to 5 mm Hg, to measure atmospheric pressure during sampling and pump calibration.
8.2.4.1.8 Rotameter. O to 100 cc/min, to detect changes in flow rate during sampling.
8.2.4.2 Sampling and Analysis.
8.2.4.2.1 Calibrate the pump and limiting orifice flow rate through adsorption tubes with the bubble tube flowmeter before sampling. The sample system can be operated as a "recirculating loop" for this operation. Record the ambient temperature and barometric pressure. Then, during sampling, use the rotameter to verify that the pump and orifice sampling rate remains constant.
8.2.4.2.2 Use a sample probe, if required, to obtain the sample at the centroid of the duct, or at a point no closer to the walls than 1 m. Minimize the length of flexible tubing between the probe and adsorption tubes. Several adsorption tubes can be connected in series, if the extra adsorptive capacity is needed. Adsorption tubes should be maintained vertically during the test in order to prevent channeling. Provide the gas sample to the sample system at a pressure sufficient for the limiting orifice to function as a sonic orifice. Record the total time and sample flow rate (or the number of pump strokes), the

barometric pressure, and ambient temperature. Obtain a total sample volume commensurate with the expected concentration(s) of the volatile organic(s) present, and recommended sample loading factors (weight sample per weight adsorption media). Laboratory tests prior to actual sampling may be necessary to predetermine this volume. If water vapor is present in the sample at concentrations above 2 to 3 percent, the adsorptive capacity may be severely reduced. Operate the gas chromatograph according to the manufacturer's instructions. After establishing optimum conditions, verify and document these conditions during all operations. Calibrate the instrument. Analyze the audit samples (see Section 16.1.4.3), then the emission samples.

8.2.4.3 Standards and Calibration. If using thermal desorption, obtain calibration gases using the procedures in Section 10.1. If using solvent extraction, prepare liquid standards in the desorption solvent. Use a minimum of three different standards; select the concentrations to bracket the expected average sample concentration. Perform the calibration before and after each day's sample analyses using the procedures in Section 8.2.1.5.2.1.

8.2.4.4 Quality Assurance.

8.2.4.4.1 Determine the recovery efficiency of the pollutants of interest according to Section 8.4.3.

8.2.4.4.2 Determination of Sample Collection Efficiency (Optional). If sample breakthrough is thought to be a problem, a routine procedure for determining breakthrough is to analyze the primary and backup portions of the adsorption tubes separately. If the backup portion exceeds 10 percent of the total amount (primary and back-up), it is usually a sign of sample breakthrough. For the purposes of this method, only the recovery efficiency value (Section 8.4.3) is used to determine the appropriateness of the sampling and analytical procedure.

8.2.4.4.3 Volume Flow Rate Checks. Perform this check immediately after sampling with all sampling train components in place. Use the bubble-tube flowmeter to measure the pump volume flow rate with the orifice used in the test sampling, and record the result. If it has changed by more than 5 but less than 20 percent, calculate an average flow rate for the test. If the flow rate has changed by more than 20 percent, recalibrate the pump and repeat the sampling.

8.2.4.4.4 Calculations. Correct all sample volumes to standard conditions. If a sample dilution system has been used, multiply the results by the appropriate dilution ratio. Correct all results according to the applicable procedure in Section 8.4.3. Report results as ppm by volume, dry basis.

8.3 Reporting of Results. At the completion of the field analysis portion of the study, ensure that the data sheets shown in Figure 18-11 have been completed. Summarize this data on the data sheets shown in Figure 18-15.

8.4 Recovery Study. After conducting the presurvey and identifying all of the pollutants of interest, conduct the appropriate recovery study during the test based on the sampling system chosen for the compounds of interest.

8.4.1 Recovery Study for Direct Interface or Dilution Interface Sampling. If the procedures in Section 8.2.2 or 8.2.3 are to be used to analyze the stack gas, conduct the calibration procedure as stated in Section 8.2.2.2 or 8.2.3.2, as appropriate. Upon successful completion of the appropriate calibration procedure, attach the mid-level calibration gas for at least one target compound to the inlet of the probe or as close as possible to the inlet of the probe, but before the filter. Repeat the calibration procedure by sampling and analyzing the mid-level calibration gas through the entire sampling and analytical system in triplicate. The mean of the calibration gas response sampled through the probe shall be within 10 percent of the analyzer response. If the difference in the two means is greater than 10 percent, check for leaks throughout the sampling system and repeat the analysis of the standard through the sampling system until this criterion is met.

8.4.2 Recovery Study for Bag Sampling.

8.4.2.1 Follow the procedures for the bag sampling and analysis in Section 8.2.1. After analyzing all three bag samples, choose one of the bag samples and tag this bag as the spiked bag. Spike the chosen bag sample with a known mixture (gaseous or liquid) of all of the target pollutants. The theoretical concentration, in ppm, of each spiked compound in the bag shall be 40 to 60 percent of the average concentration measured in the three bag samples. If a target compound was not detected in the bag samples, the concentration of that compound to be spiked shall be 5 times the limit of detection for that compound. Store the spiked bag for the same period of time as the bag samples collected in the field. After the appropriate storage time has passed, analyze the spiked bag three times. Calculate the average fraction recovered (R) of each spiked target compound with the equation in Section 12.7.

8.4.2.2 For the bag sampling technique to be considered valid for a compound, $0.70 \leq R \leq 1.30$. If the R value does not meet this criterion for a target compound, the sampling technique is not acceptable for that compound, and therefore another sampling technique shall be evaluated for acceptance (by repeating the recovery study with another sampling technique). Report the R value in the test report and correct all field measurements with the calculated R value for that compound by using the equation in Section 12.8.

8.4.3 Recovery Study for Adsorption Tube Sampling. If following the adsorption tube procedure in Section 8.2.4, conduct

a recovery study of the compounds of interest during the actual field test. Set up two identical sampling trains. Collocate the two sampling probes in the stack. The probes shall be placed in the same horizontal plane, where the first probe tip is 2.5 cm from the outside edge of the other. One of the sampling trains shall be designated the spiked train and the other the unspiked train. Spike all of the compounds of interest (in gaseous or liquid form) onto the adsorbent tube(s) in the spiked train before sampling. The mass of each spiked compound shall be 40 to 60 percent of the mass expected to be collected with the unspiked train. Sample the stack gas into the two trains simultaneously. Analyze the adsorbents from the two trains utilizing identical analytical procedures and instrumentation. Determine the fraction of spiked compound recovered (R) using the equations in Section 12.9.

8.4.3.1 Repeat the procedure in Section 8.4.3 twice more, for a total of three runs. In order for the adsorbent tube sampling and analytical procedure to be acceptable for a compound, $0.70 \leq R \leq 1.30$ (R in this case is the average of three runs). If the average R value does not meet this criterion for a target compound, the sampling technique is not acceptable for that compound, and therefore another sampling technique shall be evaluated for acceptance (by repeating the recovery study with another sampling technique). Report the R value in the test report and correct all field measurements with the calculated R value for that compound by using the equation in Section 12.8.

9.0 Quality Control.

9.1 Miscellaneous Quality Control Measures

Section	Quality Control Measure	Effect
8.4.1	Recovery study for direct interface or dilution interface sampling.	Ensure that there are no significant leaks in the sampling system.
8.4.2	Recovery study for bag sampling.	Demonstrate that proper sampling/analysis procedures were selected.
8.4.3	Recovery study for adsorption tube sampling.	Demonstrate that proper sampling/analysis procedures were selected.

9.2 Quality Assurance for Laboratory Procedures. Immediately after the preparation of the calibration curves, the analysis audit described in 40 CFR Part 61, Appendix C, Procedure 2: "Procedure for Field Auditing GC Analysis," should be performed if audit materials are available. The information required to document the analysis of the audit samples has been included on the example data sheets shown in Figures 18-3 and 18-7. The audit analyses should agree with the certified audit concentrations within 10 percent. Audit sample results shall be submitted according to directions provided with the audit samples.

10.0 Calibration and Standardization.

10.1 Calibration Standards. Obtain calibration gas standards for each target compound to be analyzed. Commercial cylinder gases certified by the manufacturer to be accurate to within 1 percent of the certified label value are preferable, although cylinder gases certified by the manufacturer to 2 percent accuracy are allowed. Another option allowed by this method is for the tester to obtain high concentration certified cylinder gases and then use a dilution system meeting the requirements of Test Method 205, 40 CFR Part 51, Appendix M to make multi-level calibration gas standards. Prepare or obtain enough calibration standards so that there are three different concentrations of each organic compound expected to be measured in the source sample. For each organic compound, select those concentrations that bracket the concentrations expected in the source samples. A calibration standard may contain more than one organic compound. If samples are collected in adsorbent tubes and extracted using solvent extraction, prepare or obtain standards in the same solvent used for the sample extraction procedure. Verify the stability of all standards for the time periods they are used.

10.2 Preparation of Calibration Curves.

10.2.1 Establish proper GC conditions, then flush the sampling loop for 30 seconds. Allow the sample loop pressure to equilibrate to atmospheric pressure, and activate the injection valve. Record the standard concentration, attenuator factor, injection time, chart speed, retention time, peak area, sample loop temperature, column temperature, and carrier gas flow rate. Analyze each standard in triplicate.

10.2.2 Repeat this procedure for each standard. Prepare a graphical plot of concentration (C_s) versus the calibration area values. Perform a regression analysis, and draw the least square line.

11.0 Analytical Procedures.

11.1 Analysis Development.

11.1.1 Selection of GC Parameters.

11.1.1.1 Column Choice. Based on the initial contact with plant personnel concerning the plant process and the anticipated emissions, choose a column that provides good resolution and rapid analysis time. The choice of an appropriate column can be aided by a literature search, contact with manufacturers of GC columns, and discussion with personnel at the emission source.

NOTE: Most column manufacturers keep excellent records on their products. Their technical service departments may be able to recommend appropriate columns and detector type for separating the anticipated compounds, and they may be able to provide information on interferences, optimum operating conditions, and column limitations. Plants with analytical laboratories may be able to provide information on their analytical procedures.

11.1.1.2 Preliminary GC Adjustment. Using the standards and column obtained in Section 11.1.1.1, perform initial tests to determine appropriate GC conditions that provide good resolution and minimum analysis time for the compounds of interest.

11.1.1.3 Preparation of Presurvey Samples. If the samples were collected on an adsorbent, extract the sample as recommended by the manufacturer for removal of the compounds with a solvent suitable to the type of GC analysis. Prepare other samples in an appropriate manner.

11.1.1.4 Presurvey Sample Analysis.

11.1.1.4.1 Before analysis, heat the presurvey sample to the duct temperature to vaporize any condensed material. Analyze the samples by the GC procedure, and compare the retention times against those of the calibration samples that contain the components expected to be in the stream. If any compounds cannot be identified with certainty by this procedure, identify them by other means such as GC/mass spectroscopy (GC/MS) or GC/infrared techniques. A GC/MS system is recommended.

11.1.1.4.2 Use the GC conditions determined by the procedure of Section 11.1.1.2 for the first injection. Vary the GC parameters during subsequent injections to determine the optimum settings. Once the optimum settings have been determined, perform repeat injections of the sample to determine the retention time of each compound. To inject a sample, draw sample through the loop at a constant rate (100 ml/min for 30 seconds). Be careful not to pressurize the gas in the loop. Turn off the pump and allow the gas in the sample loop to come to ambient pressure. Activate the sample valve, and record injection time, loop temperature, column temperature, carrier flow rate, chart speed, and attenuator setting. Calculate the retention time of each peak using the distance from injection to the peak maximum divided by the chart speed. Retention times should be repeatable within O.5 seconds.

11.1.1.4.3 If the concentrations are too high for appropriate detector response, a smaller sample loop or dilutions may be used for gas samples, and, for liquid samples, dilution with solvent is appropriate. Use the standard curves (Section 10.2) to obtain an estimate of the concentrations.

11.1.1.4.4 Identify all peaks by comparing the known retention times of compounds expected to be in the retention times of peaks in the sample. Identify any remaining unidentified peaks which have areas larger than 5 percent of the total using a GC/MS, or estimation of possible compounds by their retention times compared to known compounds, with confirmation by further GC analysis.

12.0 Data Analysis and Calculations.

12.1 Nomenclature.

B_{ws} = Water vapor content of the bag sample or stack gas, proportion by volume.

C_s = Concentration of the organic from the calibration curve, ppm.

G_v = Gas volume or organic compound injected, ml.

L_v = Liquid volume of organic injected, µl.

M = Molecular weight of organic, g/g-mole.

m_s = Total mass of compound measured on adsorbent with spiked train (µg).

m_u = Total mass of compound measured on adsorbent with unspiked train (µg).

m_v = Mass per volume of spiked compound measured (µg/L).

P_i = Barometric or absolute sample loop pressure at time of sample analysis, mm Hg.

P_m = Absolute pressure of dry gas meter, mm Hg.

P_r = Reference pressure, the barometric pressure or absolute sample loop pressure recorded during calibration, mm Hg.
P_s = Absolute pressure of syringe before injection, mm Hg.
q_c = Flow rate of the calibration gas to be diluted.
q_{c1} = Flow rate of the calibration gas to be diluted in stage 1.
q_{c2} = Flow rate of the calibration gas to be diluted in stage 2.
q_d = Diluent gas flow rate.
q_{d1} = Flow rate of diluent gas in stage 1.
q_{d2} = Flow rate of diluent gas in stage 2.
s = Theoretical concentration (ppm) of spiked target compound in the bag.
S = Theoretical mass of compound spiked onto adsorbent in spiked train (µg).
t = Measured average concentration (ppm) of target compound and source sample (analysis results subsequent to bag spiking)
T_i = Sample loop temperature at the time of sample analysis, °K.
T_m = Absolute temperature of dry gas meter, °K.
T_s = Absolute temperature of syringe before injection, °K.
u = Source sample average concentration (ppm) of target compound in the bag (analysis results before bag spiking).
V_m = Gas volume indicated by dry gas meter, liters.
v_s = volume of stack gas sampled with spiked train (L).
v_u = volume of stack gas sampled with unspiked train (L).
X = Mole or volume fraction of the organic in the calibration gas to be diluted.
Y = Dry gas meter calibration factor, dimensionless.
µl = Liquid organic density as determined, g/ml.
24.055 = Ideal gas molar volume at 293 °K and 760 mm Hg, liters/g-mole.
1000 = Conversion factor, ml/liter.
10^6 = Conversion to ppm.

12.2 Calculate the concentration, C_s, in ppm using the following equation:

$$C_s = \frac{10^6 \ (\overline{X} \ q_c)}{q_c + q_d}$$

12.3 Calculate the concentration, C_s, in ppm of the organic in the final gas mixture using the following equation:

$$C_s = 10^6 \overline{X} \left(\frac{q_{c1}}{q_{c1} + q_{d1}}\right)\left(\frac{q_{c2}}{q_{c2} + q_{d2}}\right)$$

12.4 Calculate each organic standard concentration, C_s, in ppm using the following equation:

$$C_s = \frac{G_v \prime 10^6 \frac{293 \ P_s}{T_s \ 760}}{V_m \ Y \ 293 \text{over} T_m \ \frac{P_m}{760} \ 1000}$$

$$= \frac{G_v \prime 10^3 \frac{P_s}{T_s} \frac{T_m}{P_m}}{V_m \ Y}$$

12.5 Calculate each organic standard concentration, C_s, in ppm using the following equation:

$$C_s = \frac{\frac{L_v}{M} \rho (24.055 \prime 10^6)}{V_m Y \frac{293 \ P_m}{T_m \ 760} 1000} = 6.24 \prime 10^4 \frac{L_v \rho T_m}{M V_m Y P_m}$$

12.6 Calculate the concentration, C_c, in ppm, dry basis, of each organic is the sample using the following equation:

$$C_c = \frac{C_s P_r T_r F_r}{P_i T_r (1-B_{ws})}$$

12.7 Calculate the average fraction recovered (R) of each spiked target compound using the following equation:

$$R = \frac{t-u}{s}$$

12.8 Correct all field measurements with the calculated R value for that compound using the following equation:

$$\text{Reported Result} = \frac{\text{Measured Concentration (ppm)}}{R}$$

12.9 Determine the mass per volume of spiked compound measured using the following equation:

$$m_v = \frac{m_s}{v_s} - \frac{m_u}{v_u}$$

12.10 Calculate the fraction of spiked compound recovered, R, using the following equation:

$$R = \frac{m_v \acute{} v_s}{S}$$

13.0 Method Performance.

13.1 Since a potential sample may contain a variety of compounds from various sources, a specific precision limit for the analysis of field samples is impractical. Precision in the range of 5 to 10 percent relative standard deviation (RSD) is typical for gas chromatographic techniques, but an experienced GC operator with a reliable instrument can readily achieve 5 percent RSD. For this method, the following combined GC/operator values are required.

(a) Precision. Triplicate analyses of calibration standards fall within 5 percent of their mean value.

(b) Accuracy. Analysis results of prepared audit samples are within 10 percent of preparation values.

(c) Recovery. After developing an appropriate sampling and analytical system for the pollutants of interest, conduct the procedure in Section 8.4. Conduct the appropriate recovery study in Section 8.4 at each sampling point where the method is being applied. Submit the data and results of the recovery procedure with the reporting of results under Section 8.3.

paration.

APPENDIX G

GAS CHROMATOGRAMS

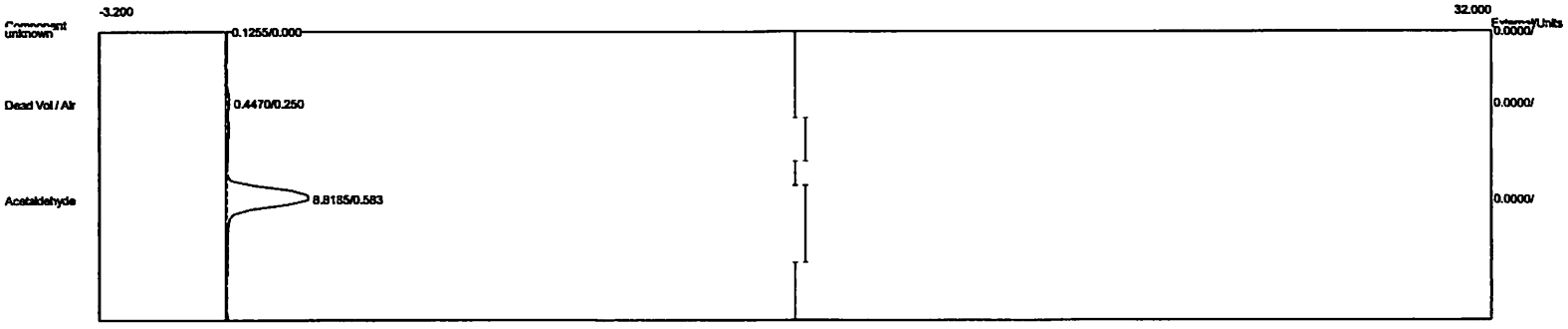
[redacted]

SCV Test #1

Sterilizers S1, S4, S8 & S9

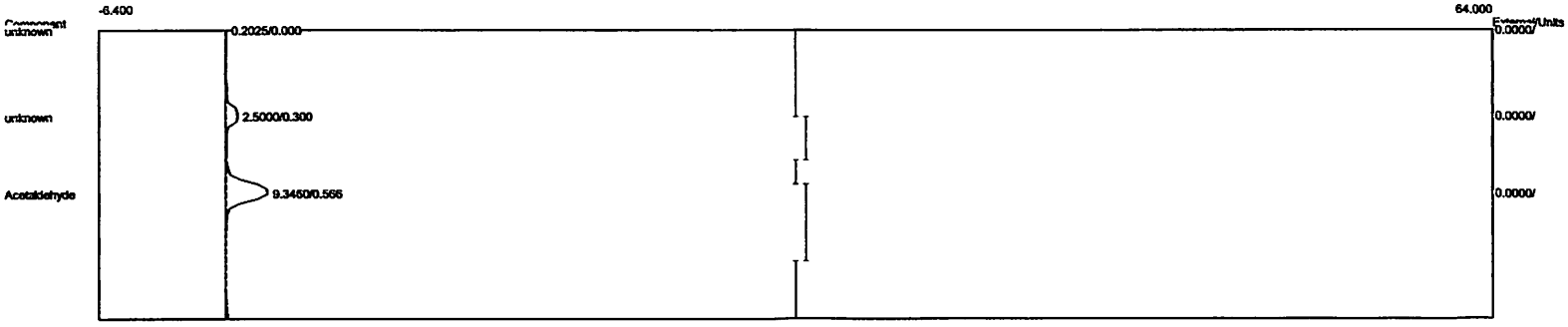
[redacted]

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 09:58:35
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E01.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



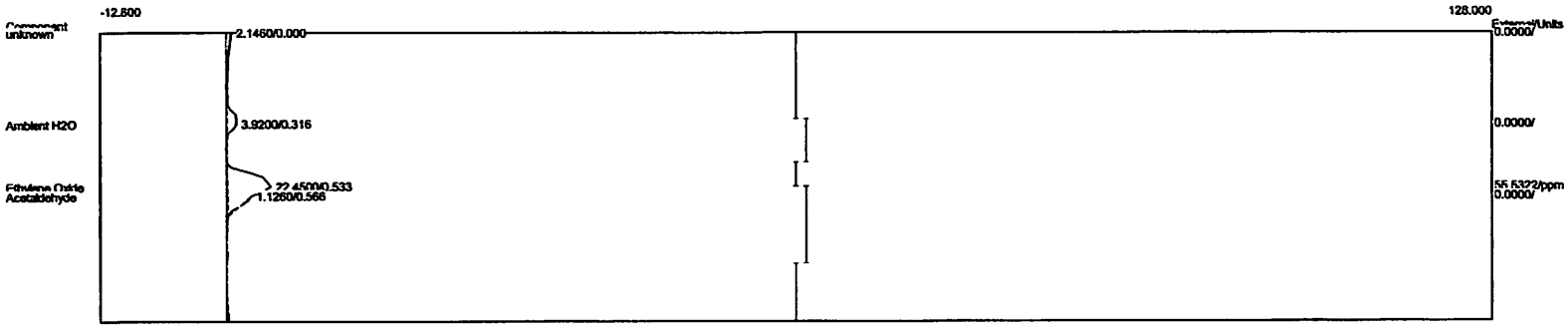
Component	Retention	Area	External	Units
Dead Vol / Air	0.250	0.4470	0.0000	
Acetaldehyde	0.583	8.8185	0.0000	
		9.2655	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 09:59:47
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E02.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



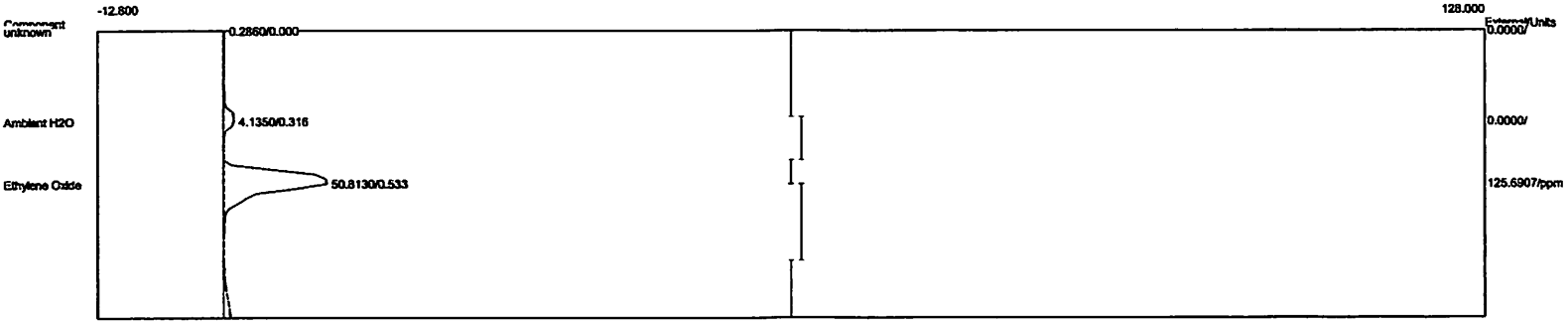
Component	Retention	Area	External	Units
Acetaldehyde	0.566	9.3460	0.0000	
		9.3460	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:00:59
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E03.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



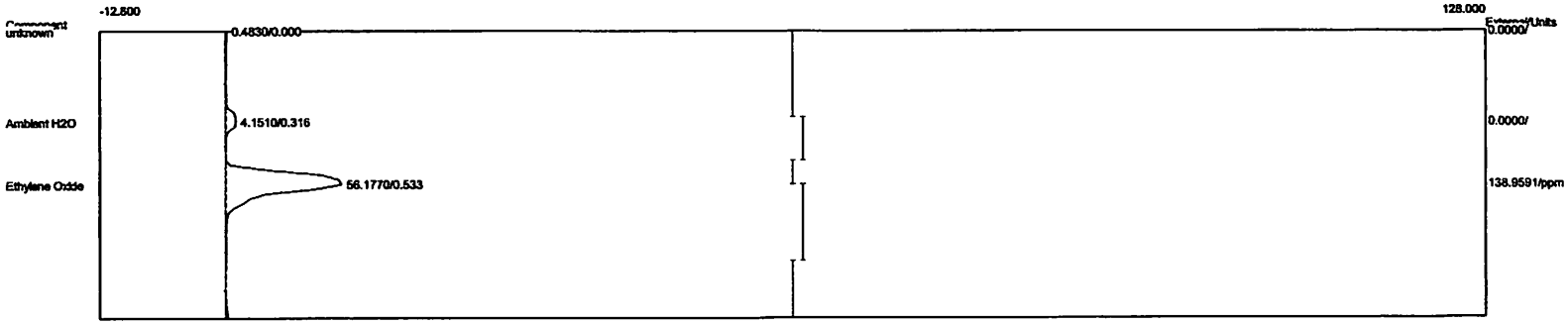
Component	Retention	Area	External	Units
Ambient H2O	0.316	3.9200	0.0000	
Ethylene Oxide	0.533	22.4500	55.5322	ppm
Acetaldehyde	0.566	1.1260	0.0000	
		27.4960	55.5322	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:02:23
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E04.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



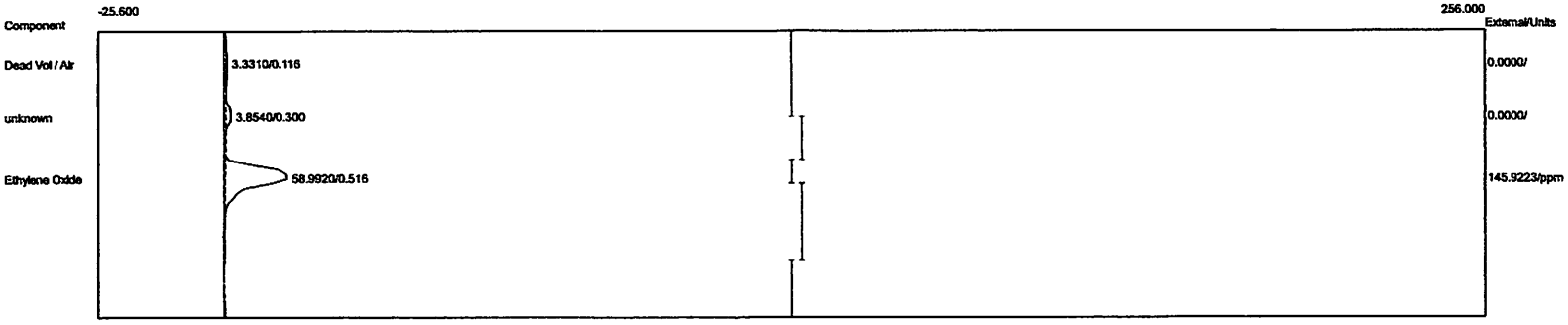
Component	Retention	Area	External	Units
Ambient H2O	0.316	4.1350	0.0000	
Ethylene Oxide	0.533	50.8130	125.6907	ppm
		54.9480	125.6907	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:03:30
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E05.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



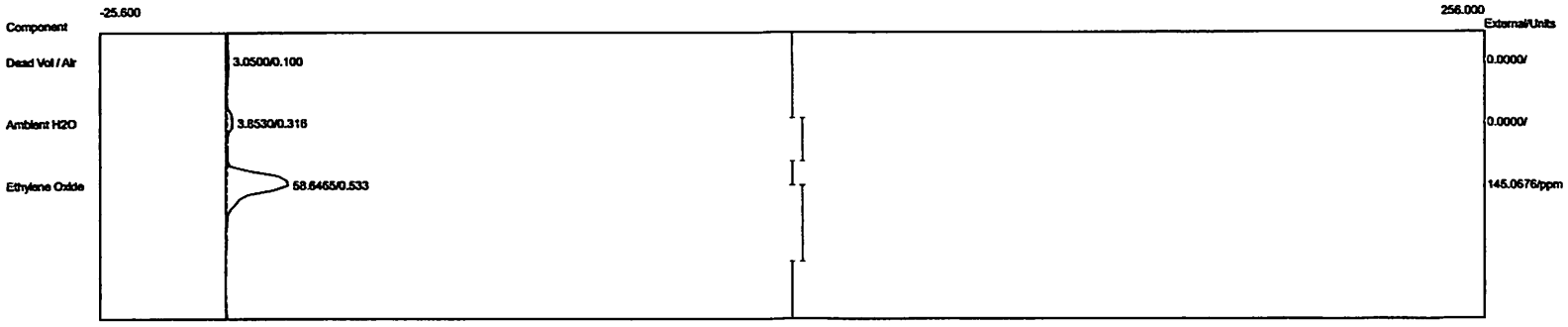
Component	Retention	Area	External	Units
Ambient H2O	0.316	4.1510	0.0000	
Ethylene Oxide	0.533	56.1770	138.9591	ppm
		60.3280	138.9591	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:04:39
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E06.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



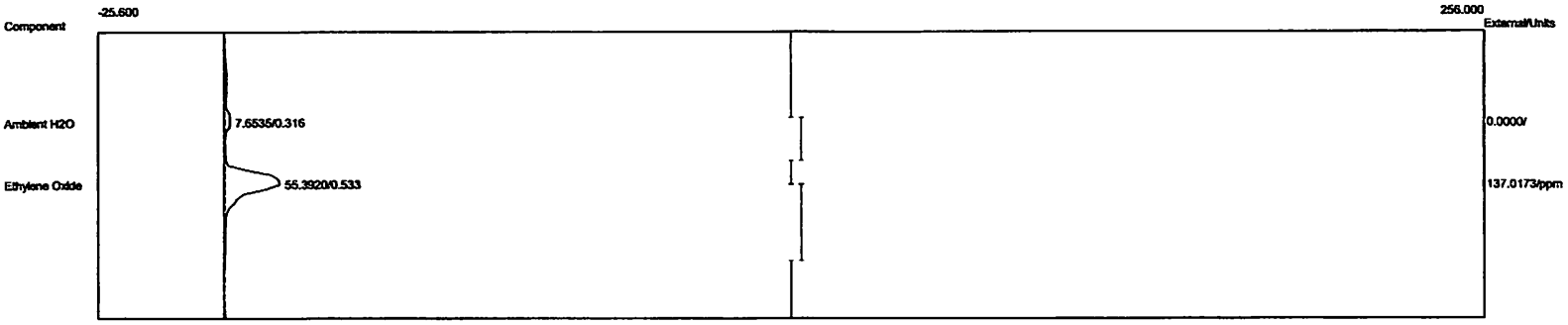
Component	Retention	Area	External	Units
Dead Vol / Air	0.116	3.3310	0.0000	
Ethylene Oxide	0.516	58.9920	145.9223	ppm
		62.3230	145.9223	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:05:48
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E07.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



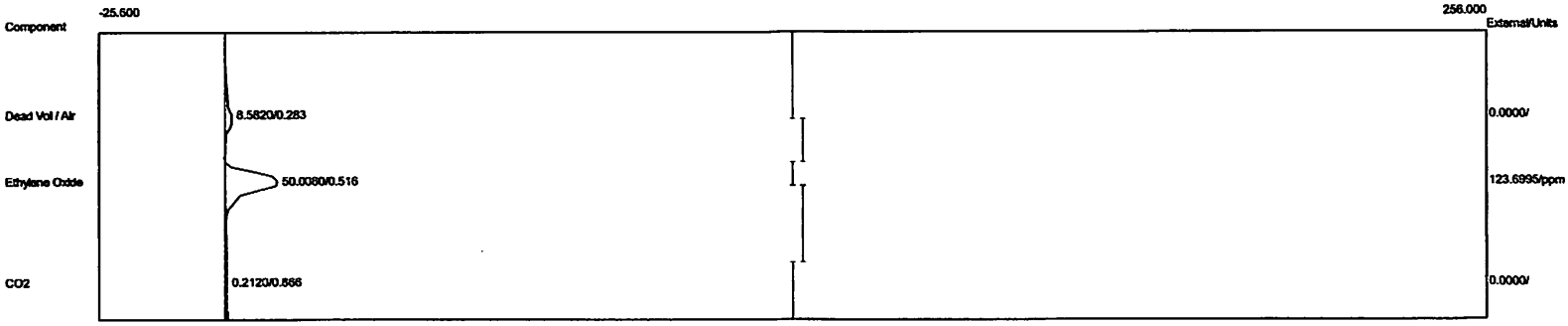
Component	Retention	Area	External	Units
Dead Vol / Air	0.100	3.0500	0.0000	
Ambient H2O	0.316	3.8530	0.0000	
Ethylene Oxide	0.533	58.6465	145.0676	ppm
		65.5495	145.0676	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:06:52
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E08.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



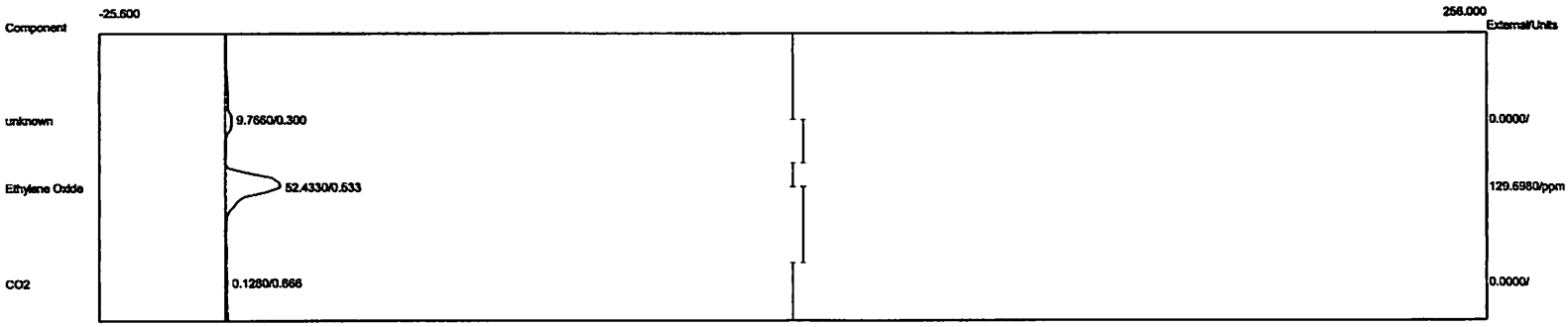
Component	Retention	Area	External	Units
Ambient H2O	0.316	7.6535	0.0000	
Ethylene Oxide	0.533	55.3920	137.0173	ppm
		63.0455	137.0173	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:07:56
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E09.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



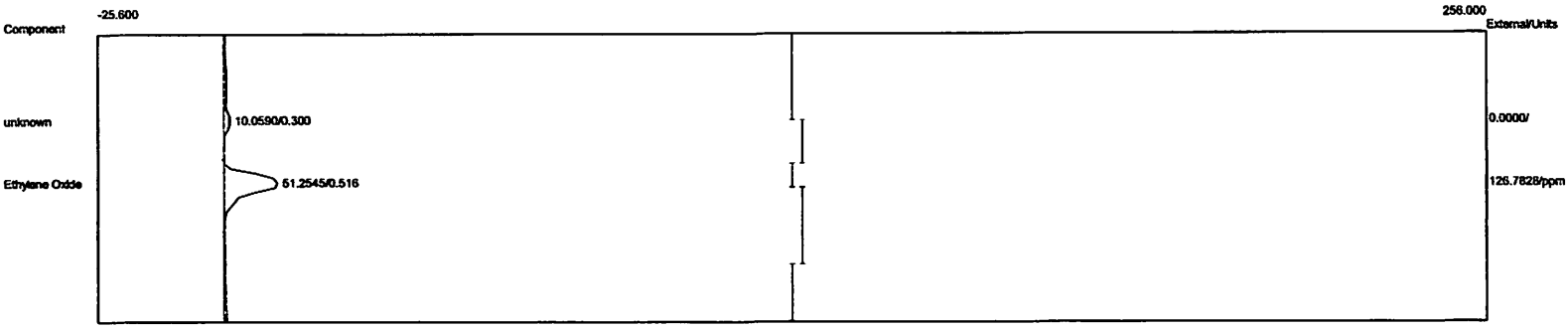
Component	Retention	Area	External	Units
Dead Vol / Air	0.283	8.5820	0.0000	
Ethylene Oxide	0.516	50.0080	123.6995	ppm
CO2	0.866	0.2120	0.0000	
		58.8020	123.6995	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:09:01
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E10.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



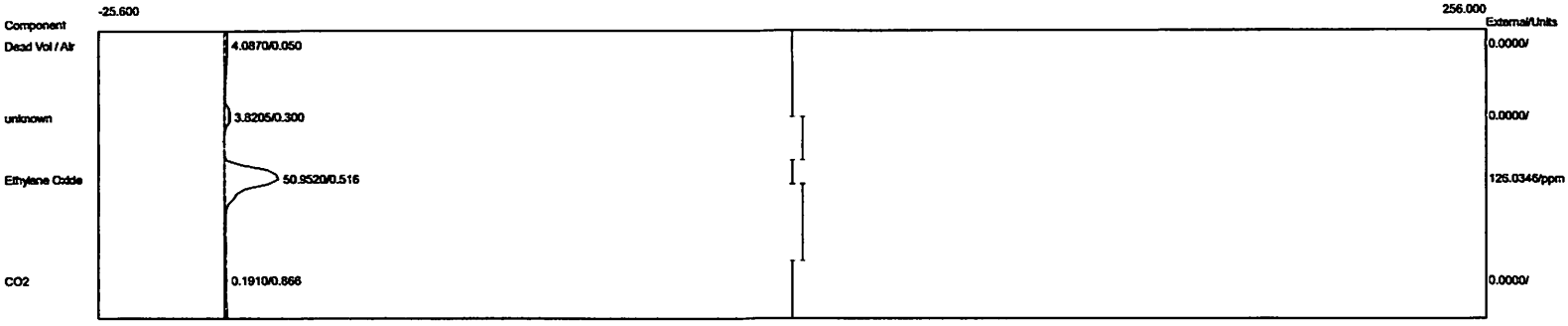
Component	Retention	Area	External	Units
Ethylene Oxide	0.533	52.4330	129.6980	ppm
CO2	0.866	0.1280	0.0000	
		52.5610	129.6980	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:10:08
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E11.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



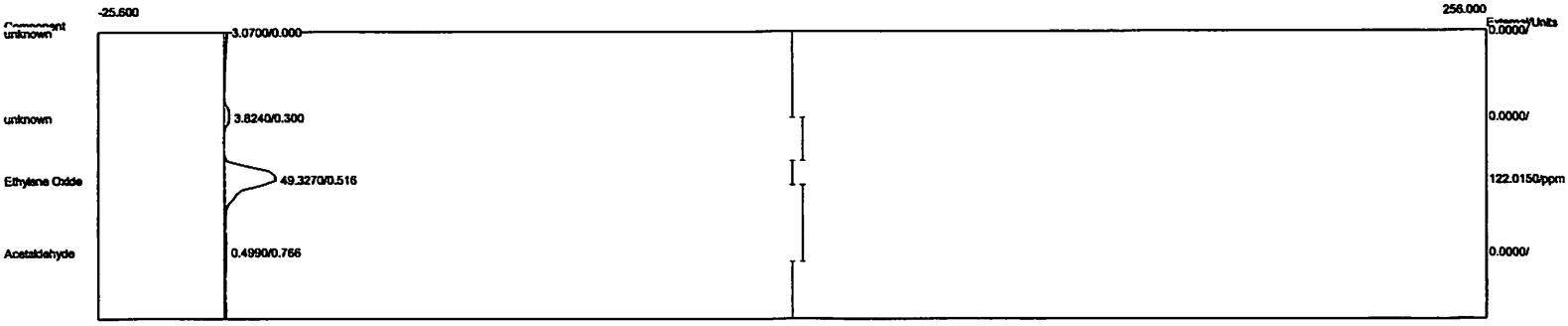
Component	Retention	Area	External	Units
Ethylene Oxide	0.516	51.2545	126.7828	ppm
		51.2545	126.7828	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:11:19
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E12.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



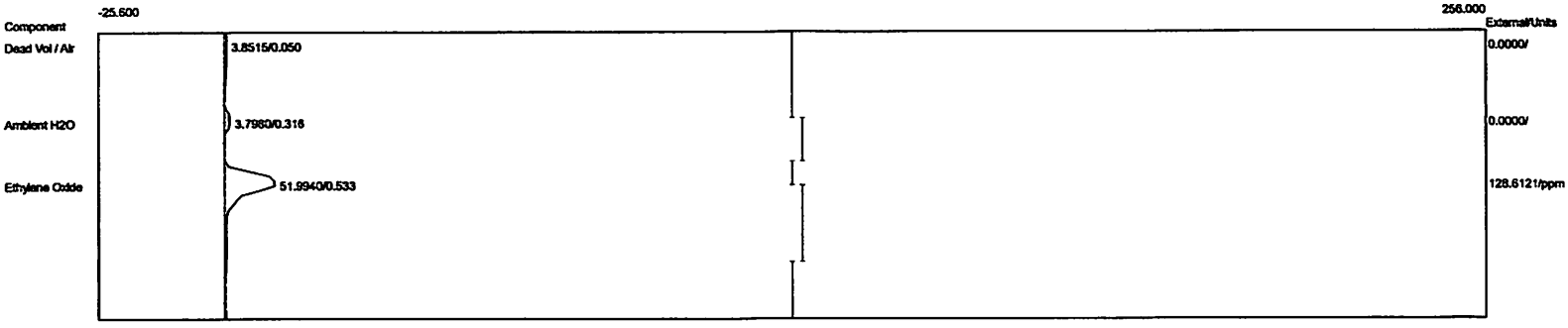
Component	Retention	Area	External	Units
Dead Vol / Air	0.050	4.0870	0.0000	
Ethylene Oxide	0.516	50.9520	126.0346	ppm
CO2	0.866	0.1910	0.0000	
		55.2300	126.0346	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:12:29
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E13.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



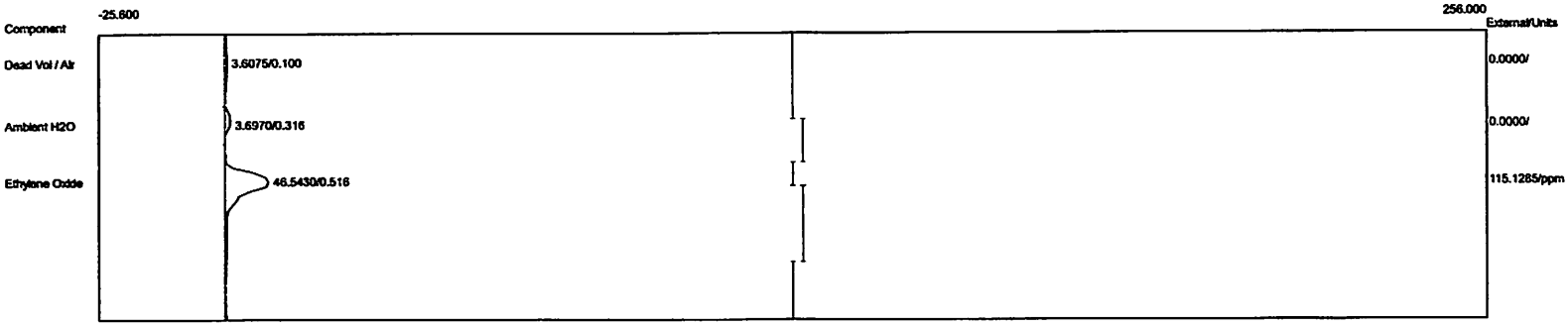
Component	Retention	Area	External	Units
Ethylene Oxide	0.516	49.3270	122.0150	ppm
Acetaldehyde	0.766	0.4990	0.0000	
		49.8260	122.0150	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:13:38
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E14.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



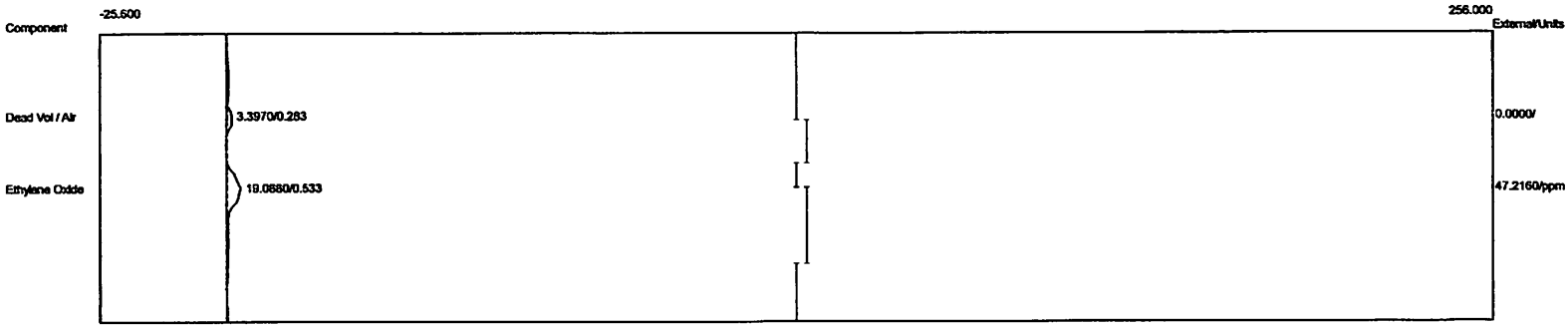
Component	Retention	Area	External	Units
Dead Vol / Air	0.050	3.8515	0.0000	
Ambient H2O	0.316	3.7980	0.0000	
Ethylene Oxide	0.533	51.9940	128.6121	ppm
		59.6435	128.6121	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:14:46
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E15.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.100	3.6075	0.0000	
Ambient H2O	0.316	3.6970	0.0000	
Ethylene Oxide	0.516	46.5430	115.1285	ppm
		53.8475	115.1285	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Exh
Analysis date: 07/27/2018 10:15:51
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1E16.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



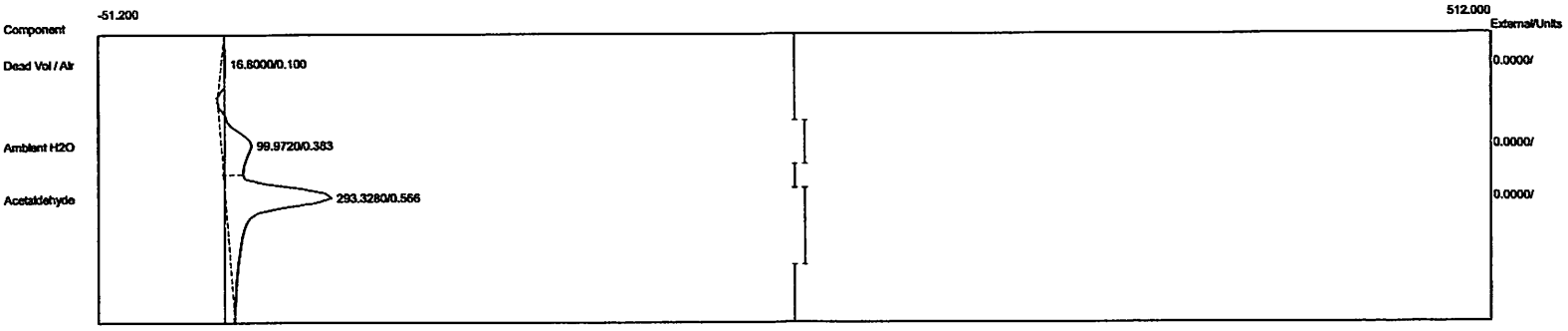
Component	Retention	Area	External	Units
Dead Vol / Air	0.283	3.3970	0.0000	
Ethylene Oxide	0.533	19.0880	47.2160	ppm
		22.4850	47.2160	

SCV Test #2

Sterilizers S8

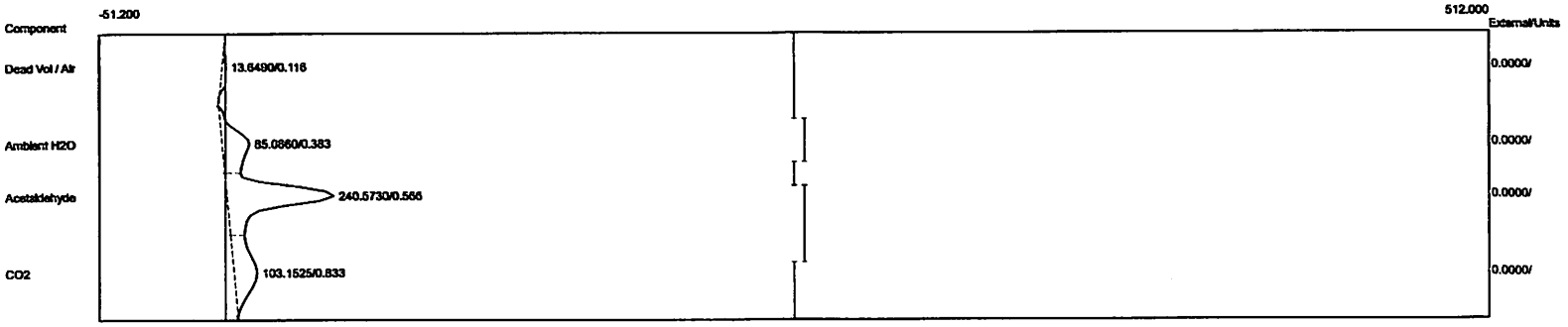
[redacted]

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:37:13
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E01.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



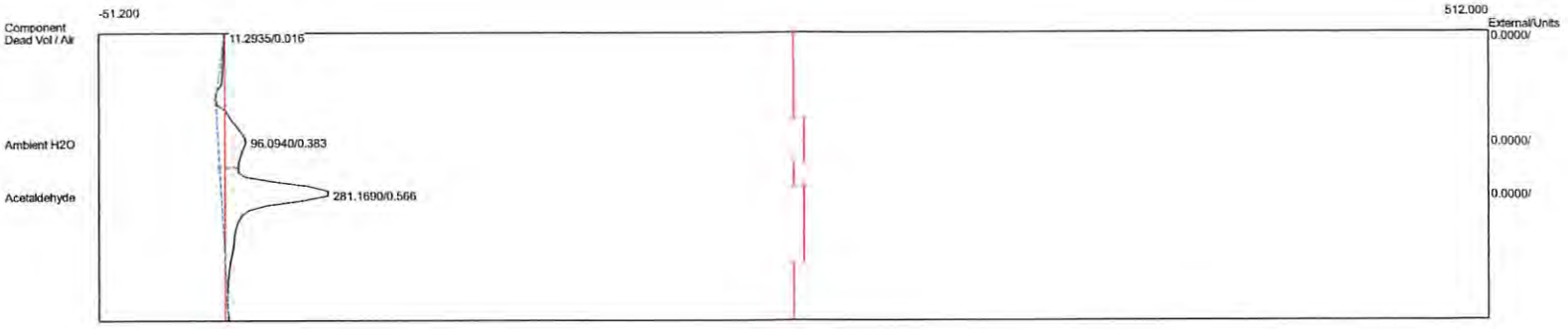
Component	Retention	Area	External	Units
Dead Vol / Air	0.100	16.8000	0.0000	
Ambient H2O	0.383	99.9720	0.0000	
Acetaldehyde	0.566	293.3280	0.0000	
		410.1000	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:38:41
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E02.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



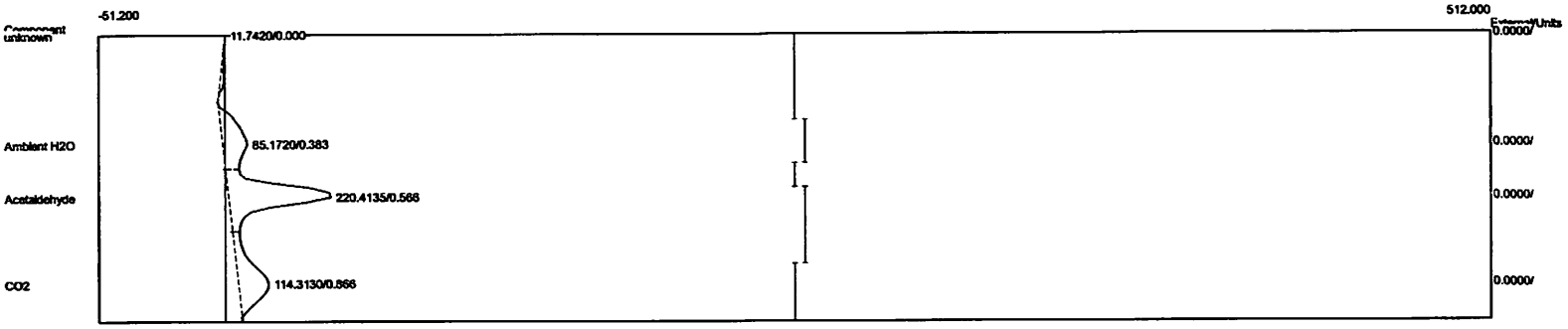
Component	Retention	Area	External	Units
Dead Vol / Air	0.116	13.6490	0.0000	
Ambient H2O	0.383	85.0860	0.0000	
Acetaldehyde	0.566	240.5730	0.0000	
CO2	0.833	103.1525	0.0000	
		442.4605	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:39:49
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E03.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



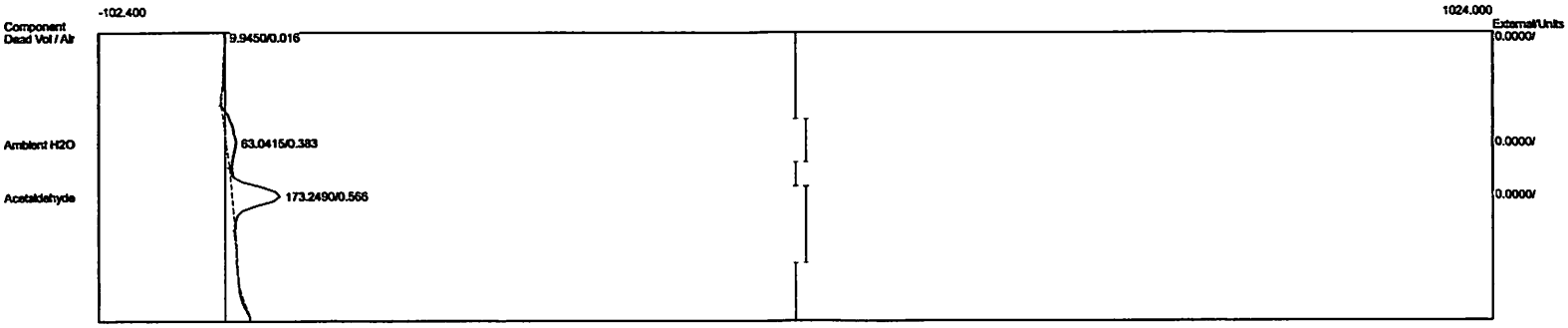
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	11.2935	0.0000	
Ambient H2O	0.383	96.0940	0.0000	
Acetaldehyde	0.566	281.1690	0.0000	
		388.5565	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:41:14
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E04.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



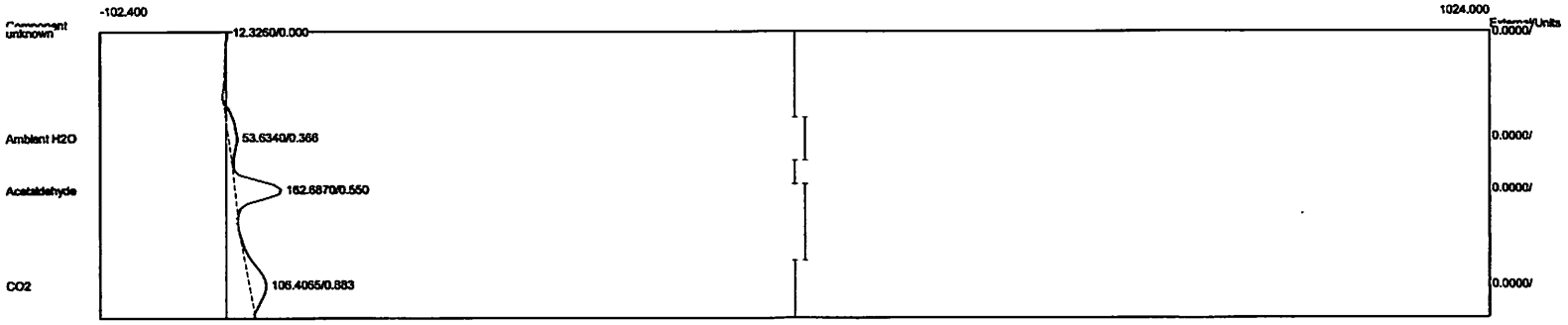
Component	Retention	Area	External	Units
Ambient H2O	0.383	85.1720	0.0000	
Acetaldehyde	0.566	220.4135	0.0000	
CO2	0.866	114.3130	0.0000	
		419.8985	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/201814:42:31
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E05.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



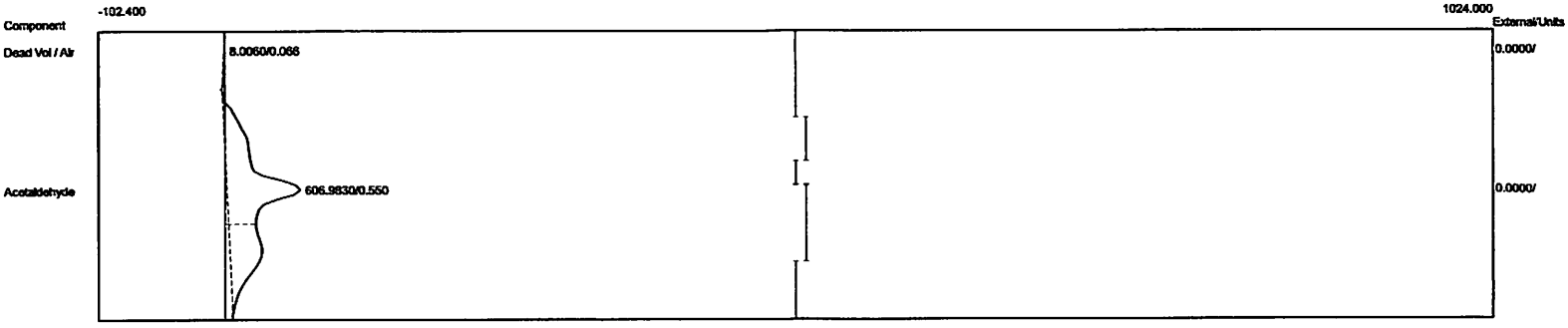
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	9.9450	0.0000	
Ambient H2O	0.383	63.0415	0.0000	
Acetaldehyde	0.566	173.2490	0.0000	
		246.2355	0.0000	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:43:55
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E06.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



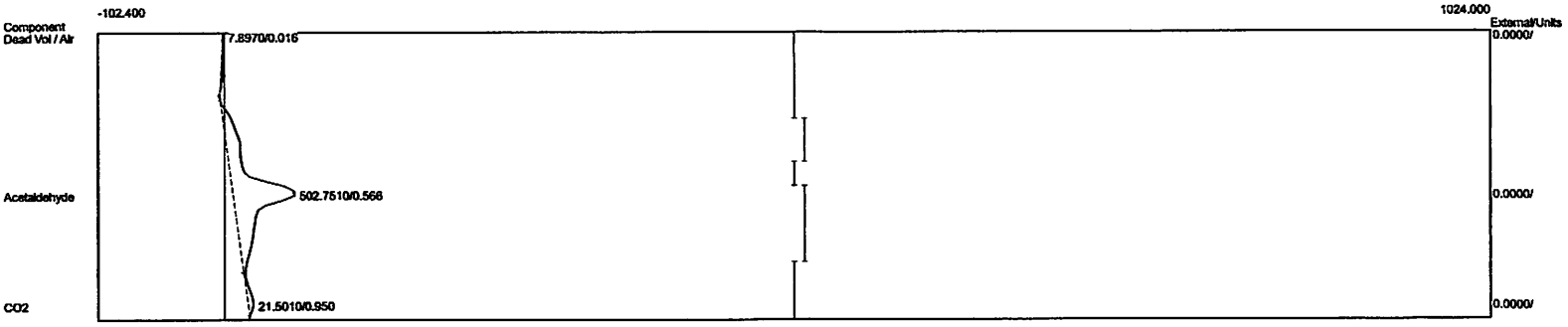
Component	Retention	Area	External	Units
Ambient H2O	0.366	53.6340	0.0000	
Acetaldehyde	0.550	162.6870	0.0000	
CO2	0.883	106.4065	0.0000	
		322.7275	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:45:25
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E07.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



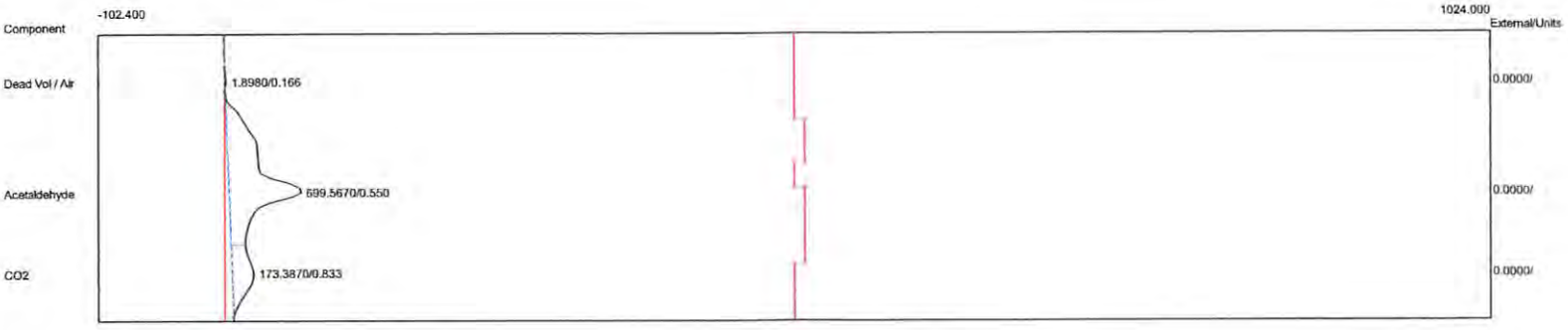
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	8.0060	0.0000	
Acetaldehyde	0.550	606.9830	0.0000	
		614.9890	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:46:45
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E08.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



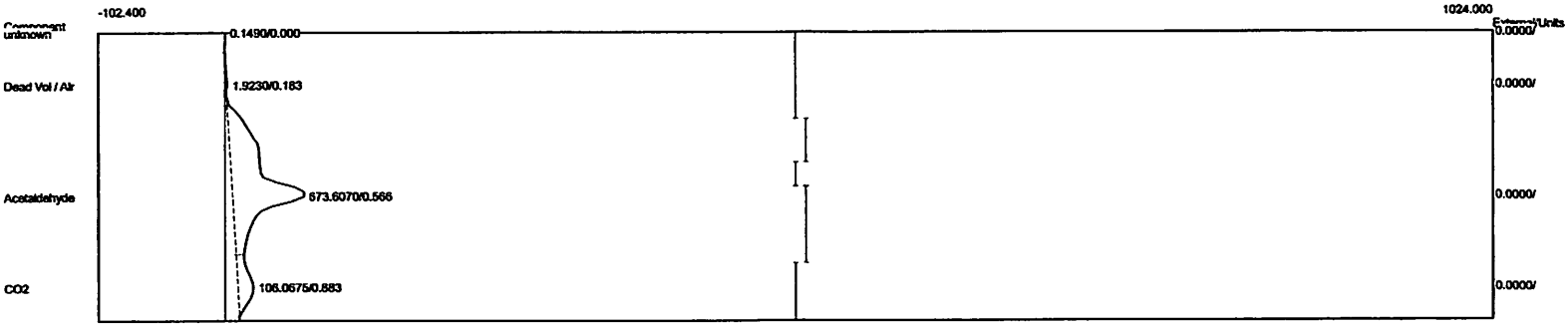
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	7.8970	0.0000	
Acetaldehyde	0.566	502.7510	0.0000	
CO2	0.950	21.5010	0.0000	
		532.1490	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:48:12
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E09.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



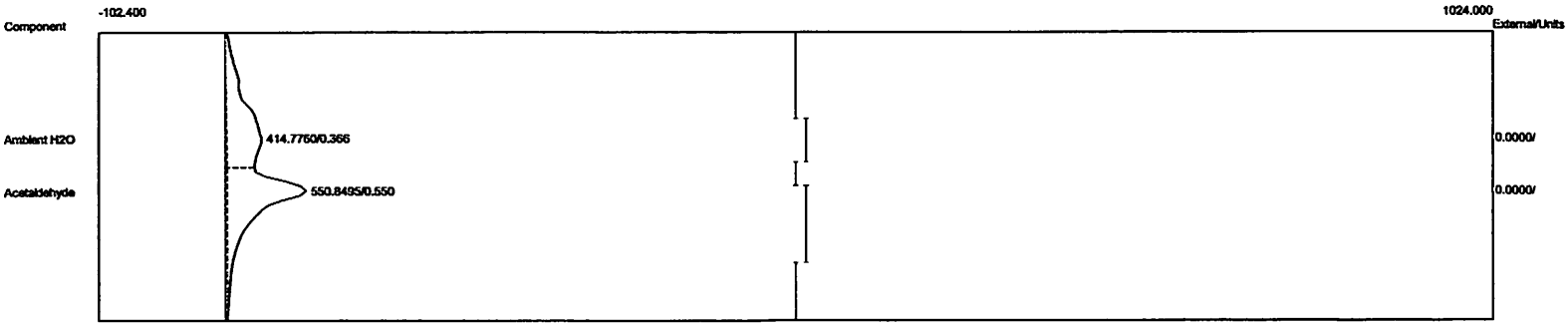
Component	Retention	Area	External	Units
Dead Vol / Air	0.166	1.8980	0.0000	
Acetaldehyde	0.550	699.5670	0.0000	
CO2	0.833	173.3870	0.0000	
		874.8520	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:49:35
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E10.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.183	1.9230	0.0000	
Acetaldehyde	0.566	673.6070	0.0000	
CO2	0.883	106.0675	0.0000	
		781.5975	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Exh
Analysis date: 07/27/2018 14:51:17
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2E11.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



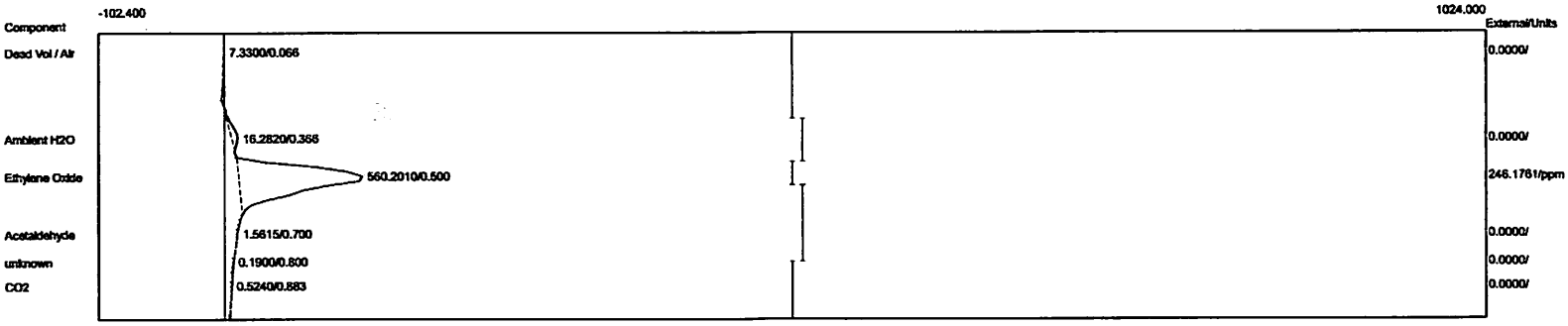
Component	Retention	Area	External	Units
Ambient H2O	0.366	414.7760	0.0000	
Acetaldehyde	0.550	550.8495	0.0000	
		965.6255	0.0000	

SCV Test #3

Sterilizers S9

[redacted]

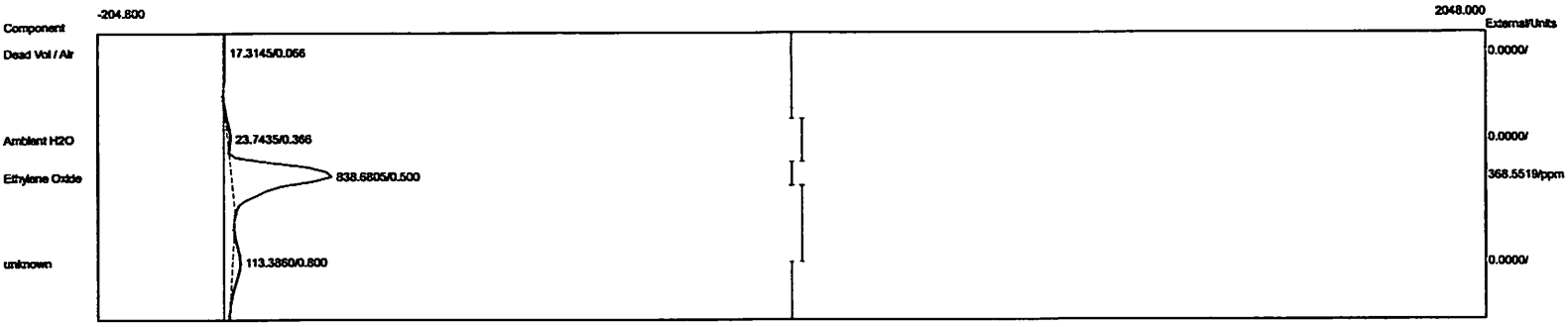
Lab name: ECSI
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/2018 14:59:10
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E01.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.066	7.3300	0.0000	
Ambient H2O	0.366	16.2820	0.0000	
Ethylene Oxide	0.500	560.2010	246.1761	ppm
Acetaldehyde	0.700	1.5615	0.0000	
CO2	0.883	0.5240	0.0000	
		585.8985	246.1761	

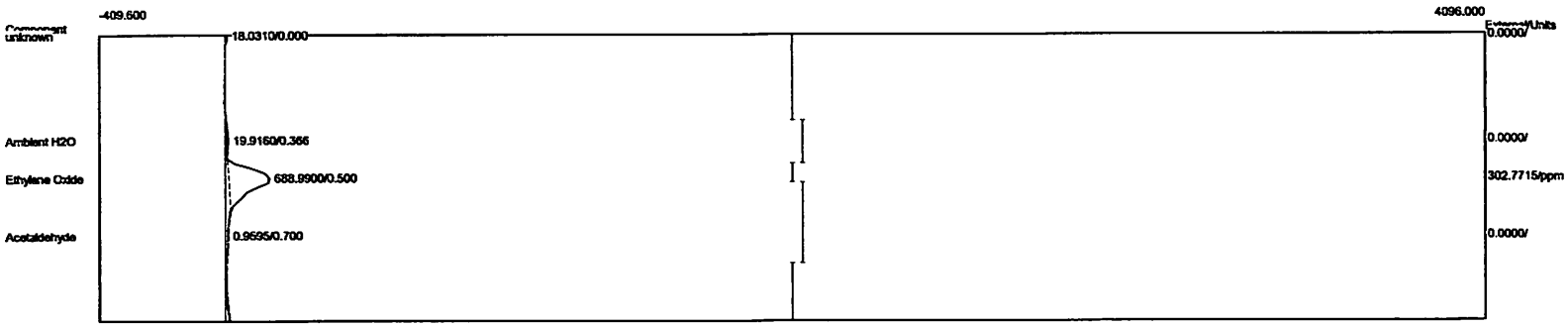
Compliance Test Chromatograms 7/27/18

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/2018 15:00:38
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E02.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



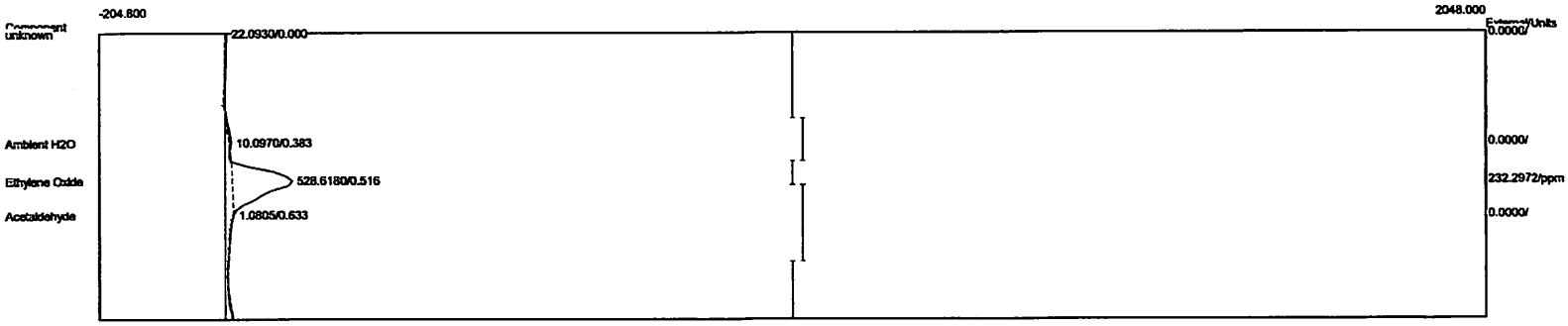
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.3145	0.0000	
Ambient H2O	0.366	23.7435	0.0000	
Ethylene Oxide	0.500	838.6805	368.5519	ppm
		879.7385	368.5519	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/201815:01:53
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E03.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



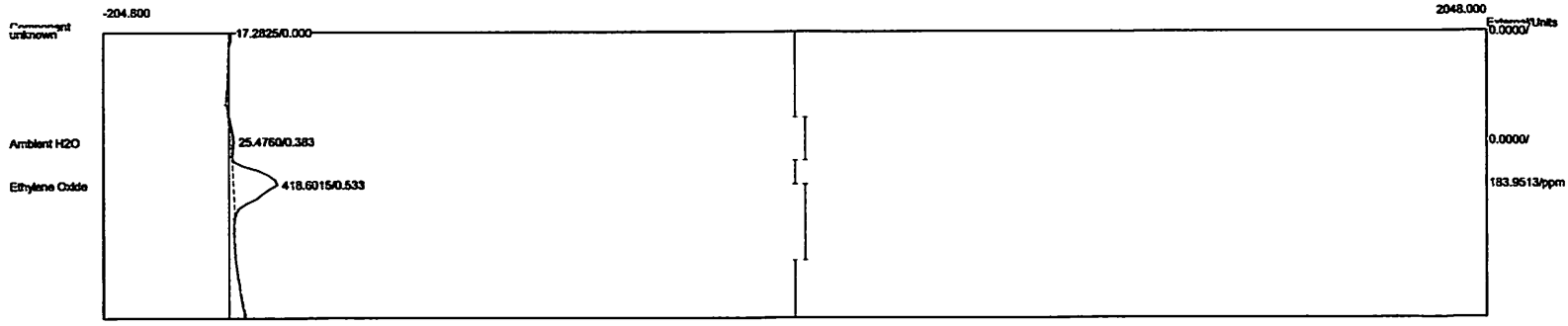
Component	Retention	Area	External	Units
Ambient H2O	0.366	19.9160	0.0000	
Ethylene Oxide	0.500	688.9900	302.7715	ppm
Acetaldehyde	0.700	0.9595	0.0000	
		709.8655	302.7715	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/2018 15:03:07
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E04.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



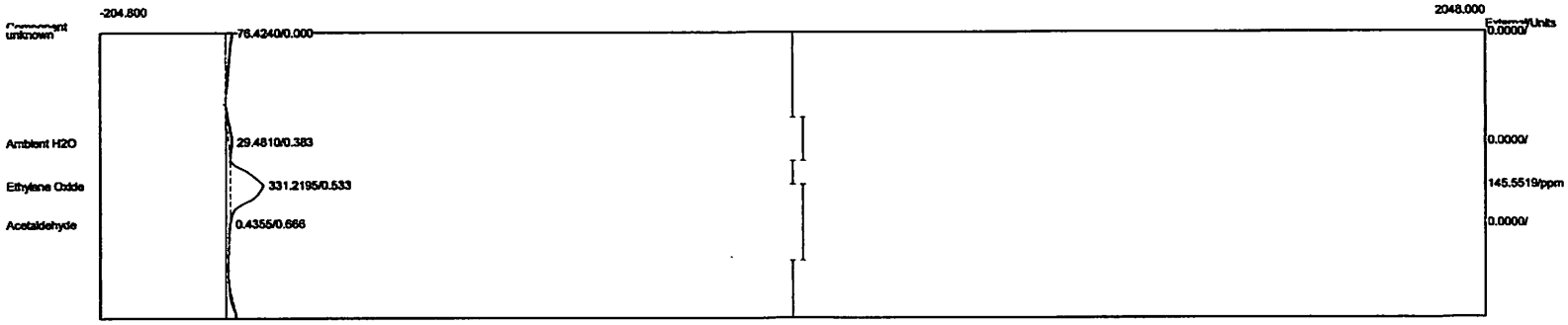
Component	Retention	Area	External	Units
Ambient H2O	0.383	10.0970	0.0000	
Ethylene Oxide	0.516	528.6180	232.2972	ppm
Acetaldehyde	0.633	1.0805	0.0000	
		539.7955	232.2972	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/2018 15:04:21
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E05.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



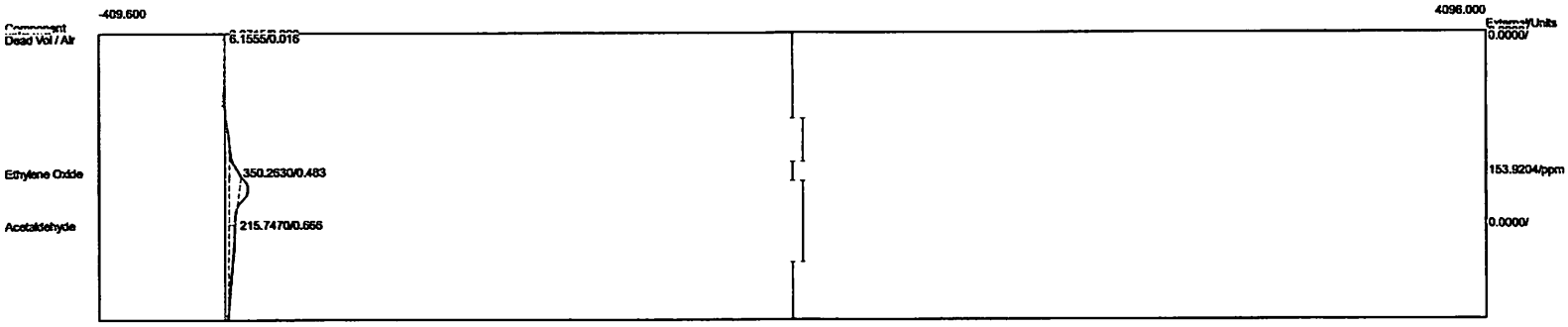
Component	Retention	Area	External	Units
Ambient H2O	0.383	25.4760	0.0000	
Ethylene Oxide	0.533	418.6015	183.9513	ppm
		444.0775	183.9513	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/2018 15:05:36
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E06.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



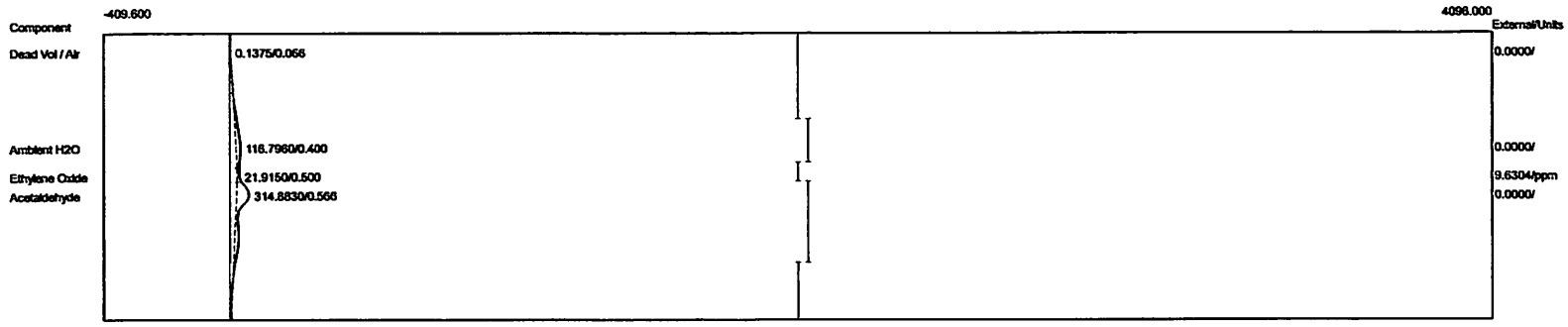
Component	Retention	Area	External	Units
Ambient H2O	0.383	29.4810	0.0000	
Ethylene Oxide	0.533	331.2195	145.5519	ppm
Acetaldehyde	0.666	0.4355	0.0000	
		361.1360	145.5519	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/201815:07:21
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E07.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



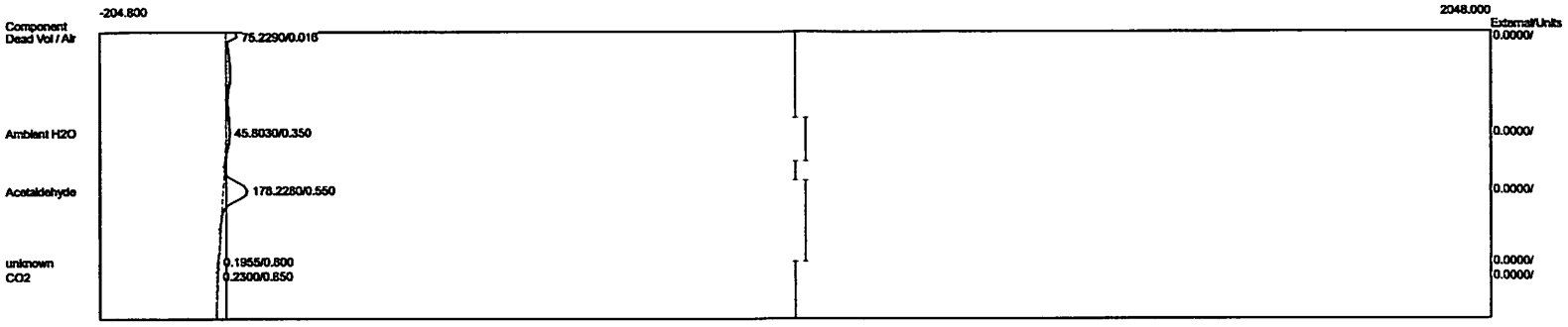
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	6.1555	0.0000	
Ethylene Oxide	0.483	350.2630	153.9204	ppm
Acetaldehyde	0.666	215.7470	0.0000	
		572.1655	153.9204	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/201815:08:56
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E08.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



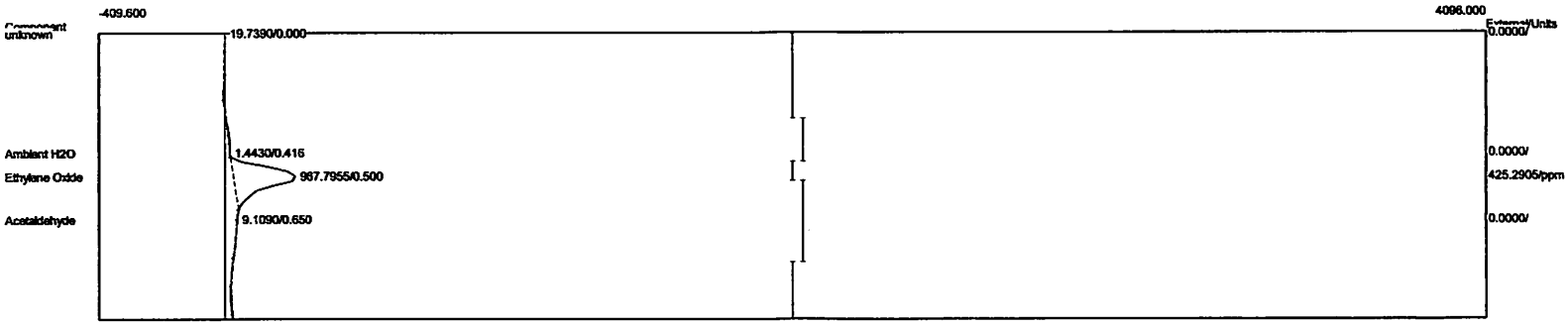
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	0.1375	0.0000	
Ambient H2O	0.400	116.7960	0.0000	
Ethylene Oxide	0.500	21.9150	9.6304	ppm
Acetaldehyde	0.566	314.8830	0.0000	
		453.7315	9.6304	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/2018 15:11:35
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E09.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



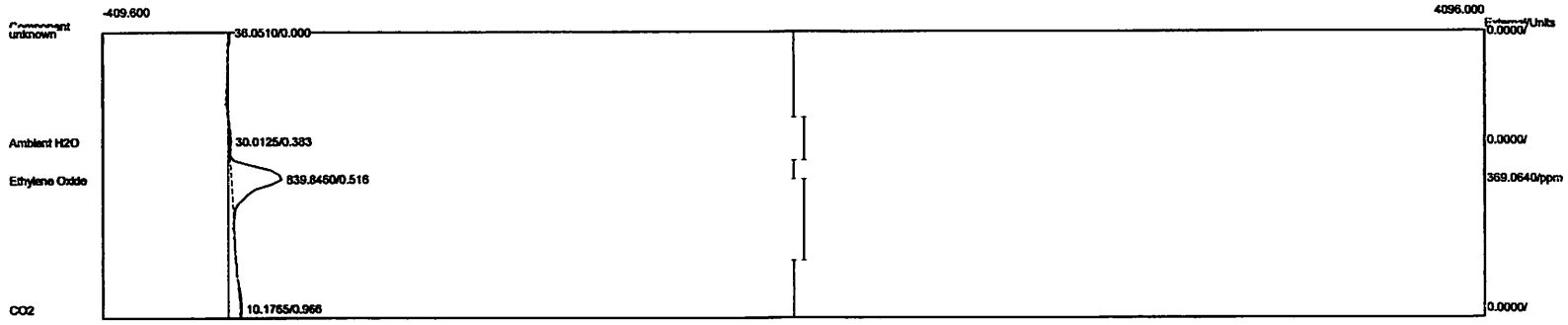
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	75.2290	0.0000	
Ambient H2O	0.350	45.8030	0.0000	
Acetaldehyde	0.550	178.2280	0.0000	
CO2	0.850	0.2300	0.0000	
		299.4900	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/201815:12:51
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E10.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Ambient H2O	0.416	1.4430	0.0000	
Ethylene Oxide	0.500	967.7955	425.2905	ppm
Acetaldehyde	0.650	9.1090	0.0000	
		978.3475	425.2905	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Exh
Analysis date: 07/27/2018 15:14:10
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3E11.CHR (c:\peak359)
Sample: Packed Tower Outlet
Operator: D. Kremer

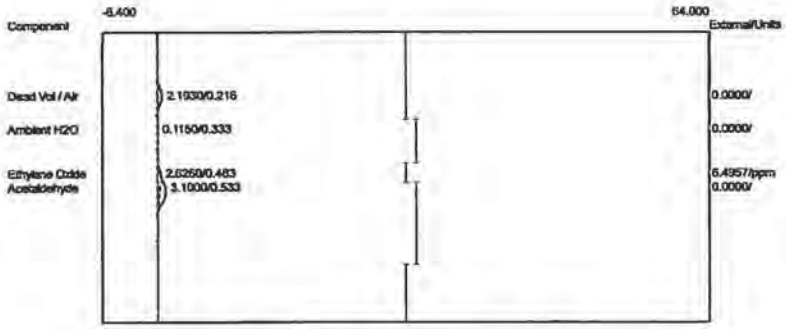


Component	Retention	Area	External	Units
Ambient H2O	0.383	30.0125	0.0000	
Ethylene Oxide	0.516	839.8460	369.0640	ppm
CO2	0.966	10.1765	0.0000	
		880.0350	369.0640	

ARV Runs #1 through #3

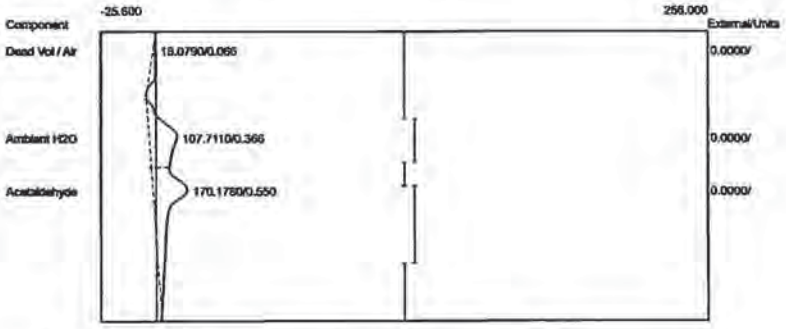
[redacted]*

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:23:39
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A12.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



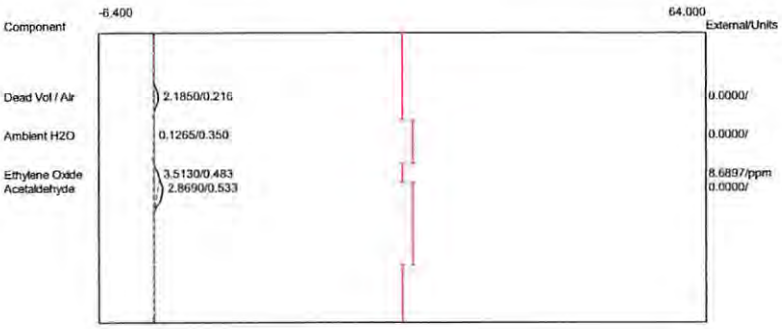
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1930	0.0000	
Ambient H2O	0.333	0.1150	0.0000	
Ethylene Oxide	0.483	2.6260	6.4957	ppm
Acetaldehyde	0.533	3.1000	0.0000	
		8.0340	6.4957	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:23:39
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A12.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



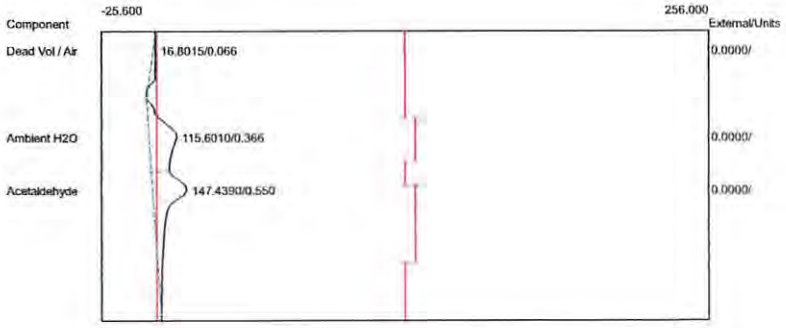
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	18.0790	0.0000	
Ambient H2O	0.366	107.7110	0.0000	
Acetaldehyde	0.550	170.1780	0.0000	
		295.9680	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:18:19
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A11.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



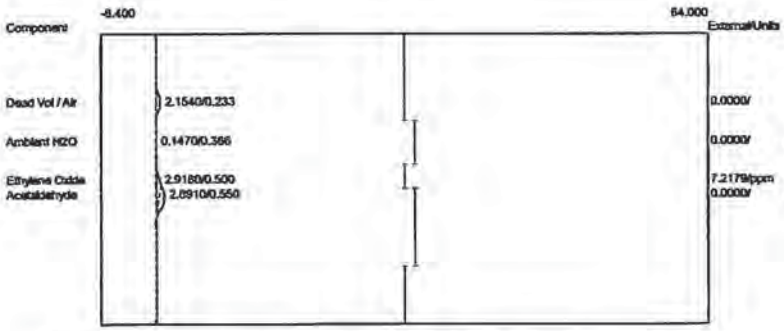
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1850	0.0000	
Ambient H2O	0.350	0.1265	0.0000	
Ethylene Oxide	0.483	3.5130	8.6897	ppm
Acetaldehyde	0.533	2.8690	0.0000	
		8.6935	8.6897	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:18:19
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A11.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



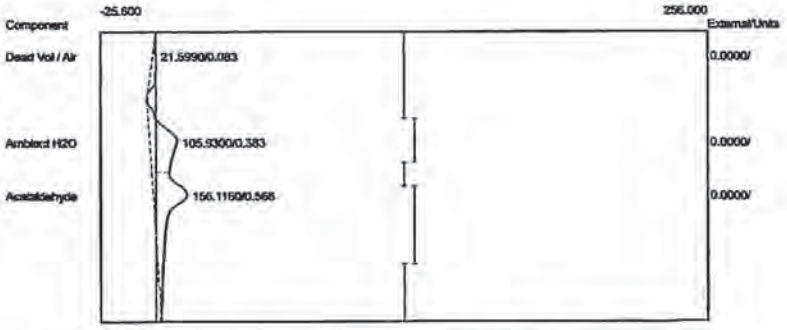
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	16.8015	0.0000	
Ambient H2O	0.366	115.6010	0.0000	
Acetaldehyde	0.550	147.4390	0.0000	
		279.8415	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:13:18
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A10.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



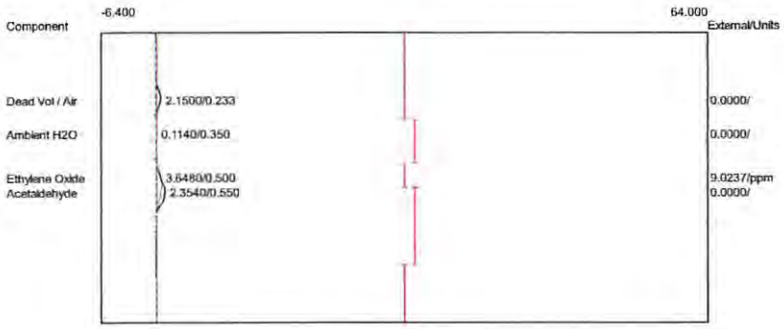
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1540	0.0000	
Ambient H2O	0.366	0.1470	0.0000	
Ethylene Oxide	0.500	2.9180	7.2179	ppm
Acetaldehyde	0.550	2.8910	0.0000	
		8.1100	7.2179	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:13:18
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A10.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



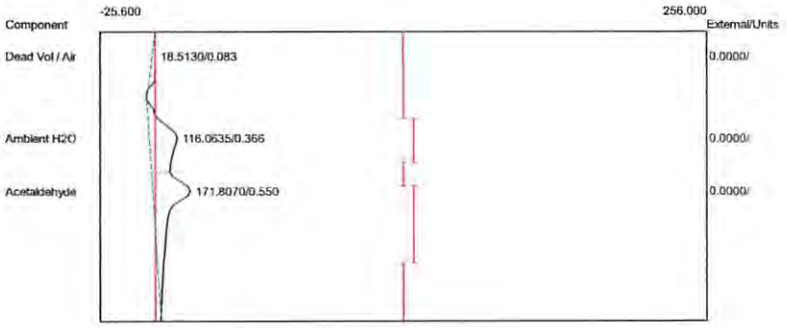
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.5990	0.0000	
Ambient H2O	0.383	105.9300	0.0000	
Acetaldehyde	0.566	156.1160	0.0000	
		283.6450	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:08:33
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A09.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



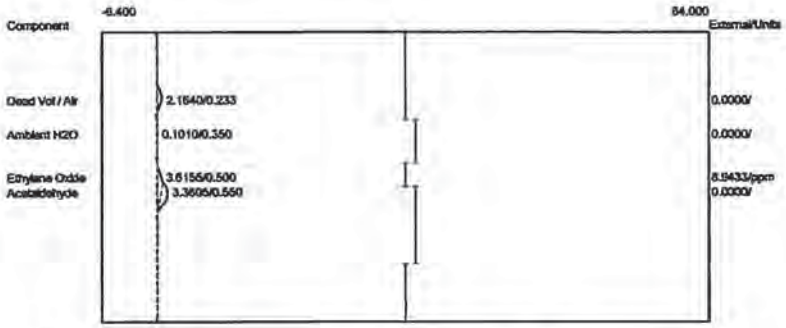
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1500	0.0000	
Ambient H2O	0.350	0.1140	0.0000	
Ethylene Oxide	0.500	3.6480	9.0237	ppm
Acetaldehyde	0.550	2.3540	0.0000	
		8.2660	9.0237	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:08:33
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A09.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



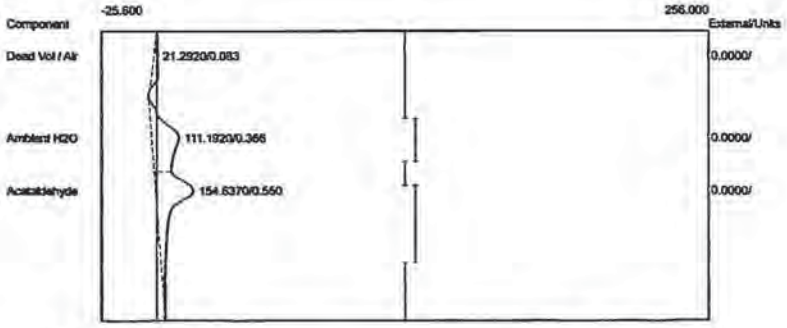
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	18.5130	0.0000	
Ambient H2O	0.366	116.0635	0.0000	
Acetaldehyde	0.550	171.8070	0.0000	
		306.3835	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:03:07
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A08.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



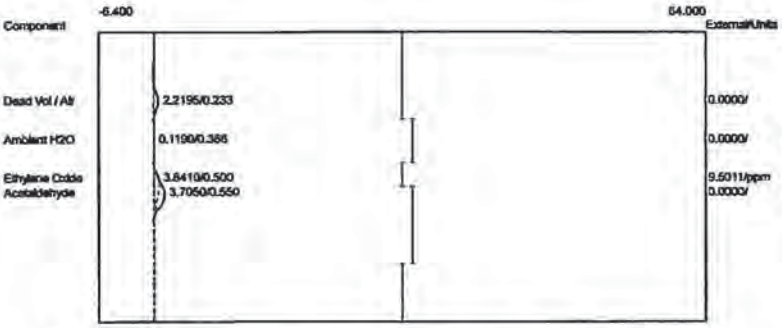
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1640	0.0000	
Ambient H2O	0.350	0.1010	0.0000	
Ethylene Oxide	0.500	3.6155	8.9433	ppm
Acetaldehyde	0.550	3.3605	0.0000	
		9.2410	8.9433	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:03:07
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A08.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



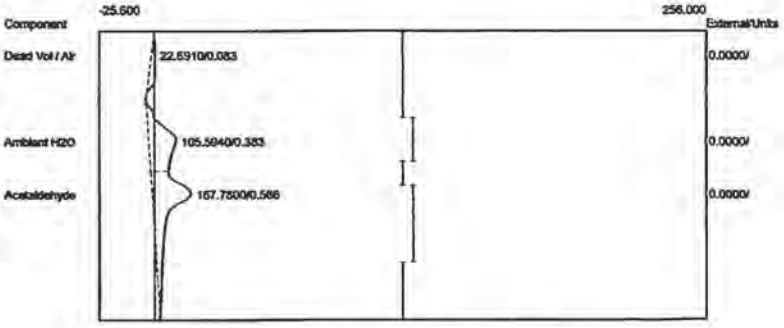
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.2920	0.0000	
Ambient H2O	0.366	111.1920	0.0000	
Acetaldehyde	0.550	154.6370	0.0000	
		287.1210	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:58:06
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A07.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



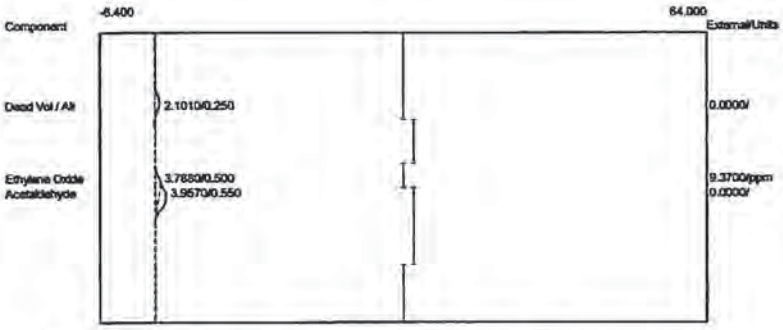
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.2195	0.0000	
Ambient H2O	0.366	0.1190	0.0000	
Ethylene Oxide	0.500	3.8410	9.5011	ppm
Acetaldehyde	0.550	3.7050	0.0000	
		9.8845	9.5011	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:58:06
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A07.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



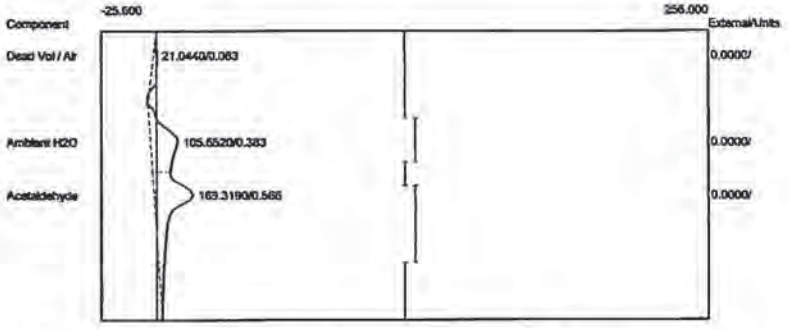
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	22.6910	0.0000	
Ambient H2O	0.383	105.5940	0.0000	
Acetaldehyde	0.566	167.7800	0.0000	
		296.0650	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:53:36
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A06.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



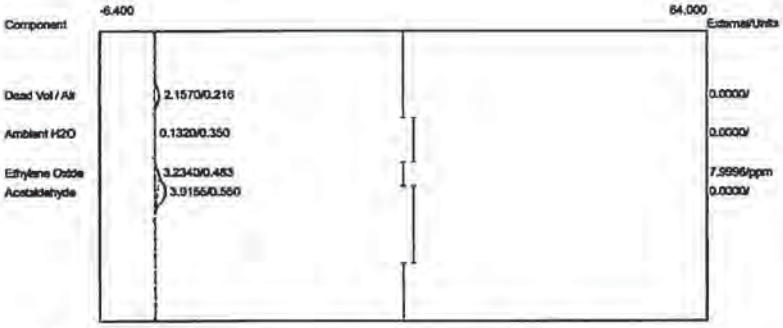
Component	Retention	Area	External	Units
Dead Vol / Air	0.250	2.1010	0.0000	
Ethylene Oxide	0.500	3.7880	9.3700	ppm
Acetaldehyde	0.550	3.9570	0.0000	
		9.8460	9.3700	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:53:36
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A06.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



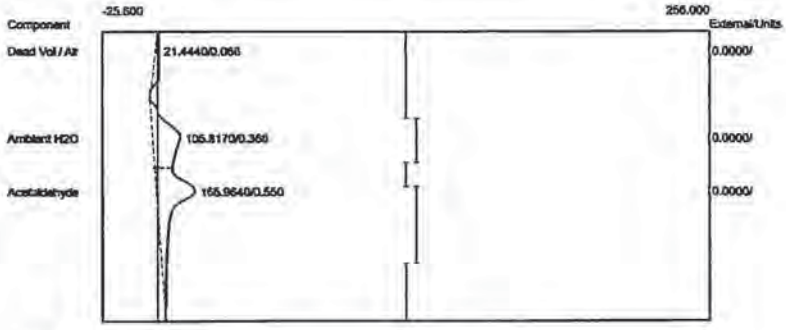
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.0440	0.0000	
Ambient H2O	0.383	105.6520	0.0000	
Acetaldehyde	0.566	169.3190	0.0000	
		296.0150	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:48:44
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A05.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



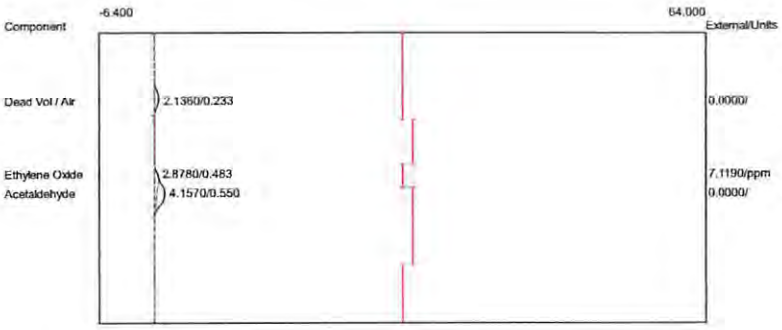
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1570	0.0000	
Ambient H2O	0.350	0.1320	0.0000	
Ethylene Oxide	0.483	3.2340	7.9996	ppm
Acetaldehyde	0.550	3.9155	0.0000	
		9.4385	7.9996	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:48:44
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A05.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



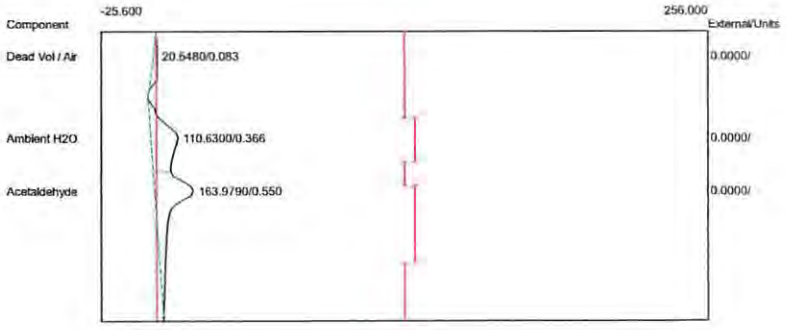
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	21.4440	0.0000	
Ambient H2O	0.366	105.8170	0.0000	
Acetaldehyde	0.550	165.9640	0.0000	
		293.2250	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:43:37
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A04.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



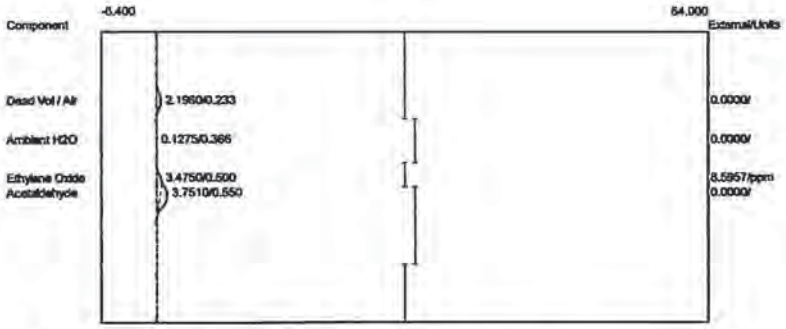
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1360	0.0000	
Ethylene Oxide	0.483	2.8780	7.1190	ppm
Acetaldehyde	0.550	4.1570	0.0000	
		9.1710	7.1190	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:43:37
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A04.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



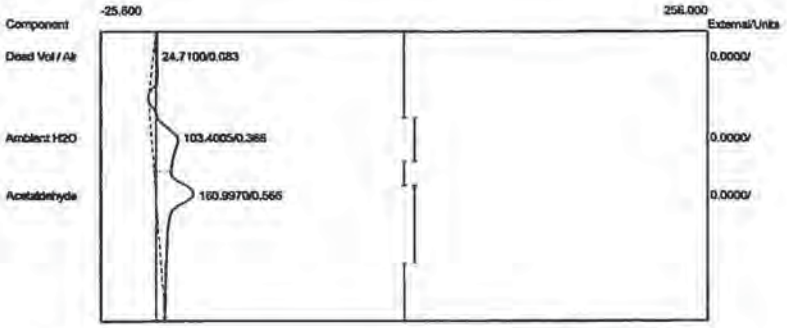
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	20.5480	0.0000	
Ambient H2O	0.366	110.6300	0.0000	
Acetaldehyde	0.550	163.9790	0.0000	
		295.1570	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:38:22
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A03.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



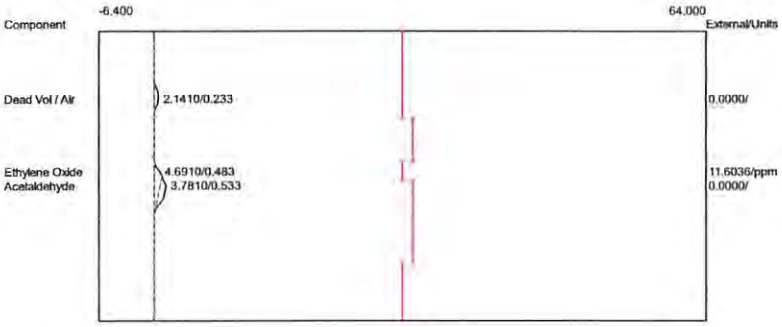
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1960	0.0000	
Ambient H2O	0.366	0.1275	0.0000	
Ethylene Oxide	0.500	3.4750	8.5957	ppm
Acetaldehyde	0.550	3.7510	0.0000	
		9.5495	8.5957	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:38:22
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A03.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



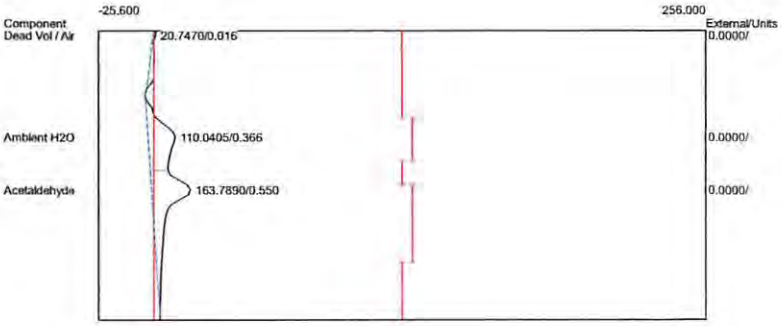
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	24.7100	0.0000	
Ambient H2O	0.366	103.4005	0.0000	
Acetaldehyde	0.566	160.9970	0.0000	
		289.1075	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:33:13
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A02.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



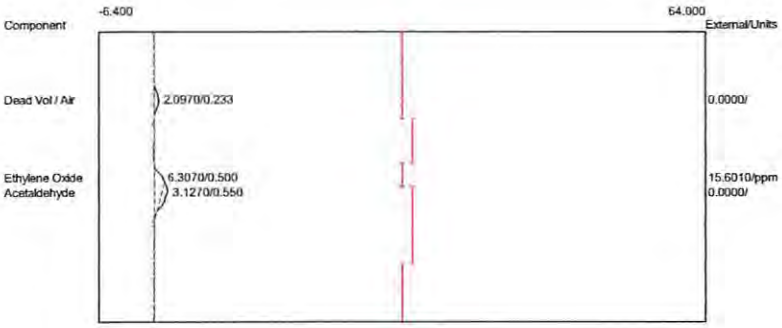
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1410	0.0000	
Ethylene Oxide	0.483	4.6910	11.6036	ppm
Acetaldehyde	0.533	3.7810	0.0000	
		10.6130	11.6036	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:33:13
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A02.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



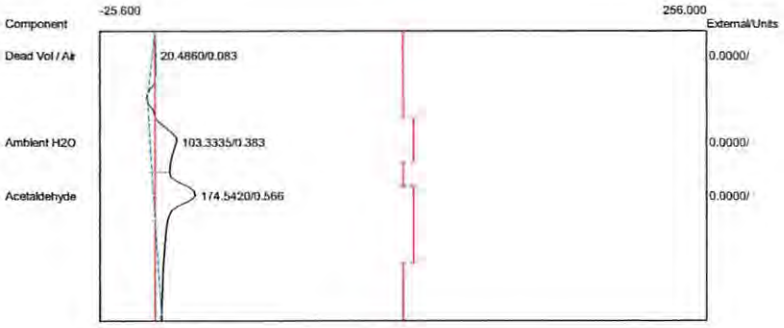
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	20.7470	0.0000	
Ambient H2O	0.366	110.0405	0.0000	
Acetaldehyde	0.550	163.7890	0.0000	
		294.5765	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:28:16
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A01.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



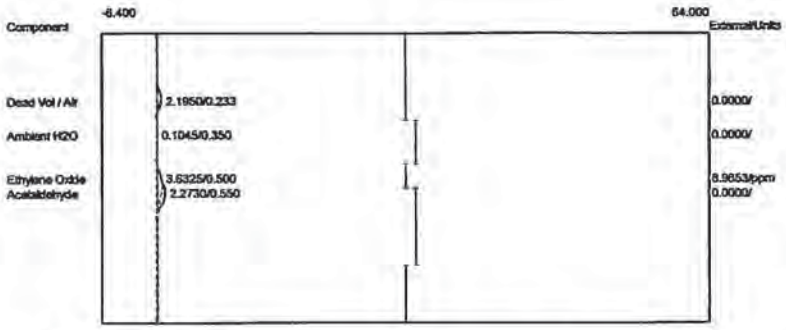
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.0970	0.0000	
Ethylene Oxide	0.500	6.3070	15.6010	ppm
Acetaldehyde	0.550	3.1270	0.0000	
		11.5310	15.6010	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:28:16
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A01.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



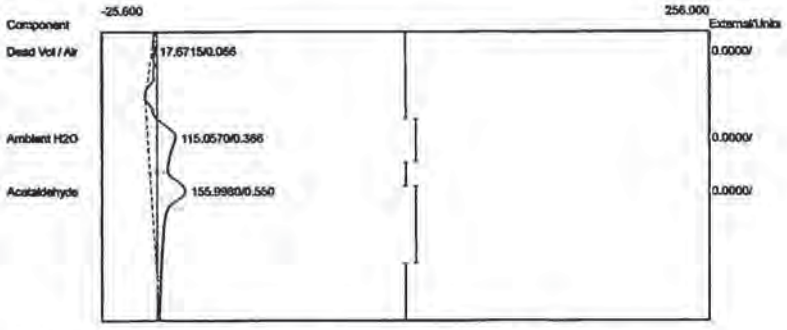
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	20.4860	0.0000	
Ambient H2O	0.383	103.3335	0.0000	
Acetaldehyde	0.566	174.5420	0.0000	
		298.3615	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:23:13
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A12.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



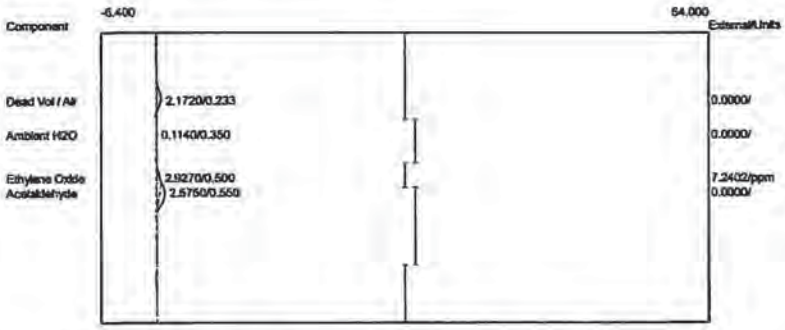
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1950	0.0000	
Ambient H2O	0.350	0.1045	0.0000	
Ethylene Oxide	0.500	3.6325	8.9853	ppm
Acetaldehyde	0.550	2.2730	0.0000	
		8.2050	8.9853	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:23:13
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A12.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



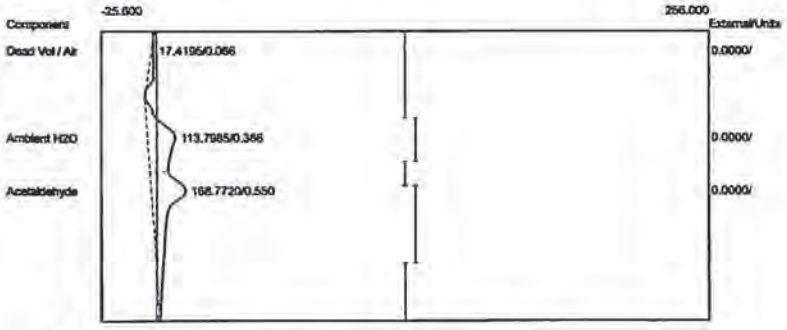
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.6715	0.0000	
Ambient H2O	0.366	115.0570	0.0000	
Acetaldehyde	0.550	155.9980	0.0000	
		288.7265	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:18:26
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A11.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



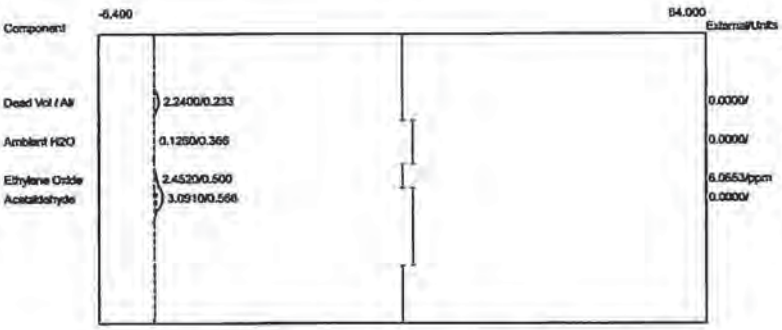
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1720	0.0000	
Ambient H2O	0.350	0.1140	0.0000	
Ethylene Oxide	0.500	2.9270	7.2402	ppm
Acetaldehyde	0.550	2.5750	0.0000	
		7.7880	7.2402	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:18:26
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A11.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



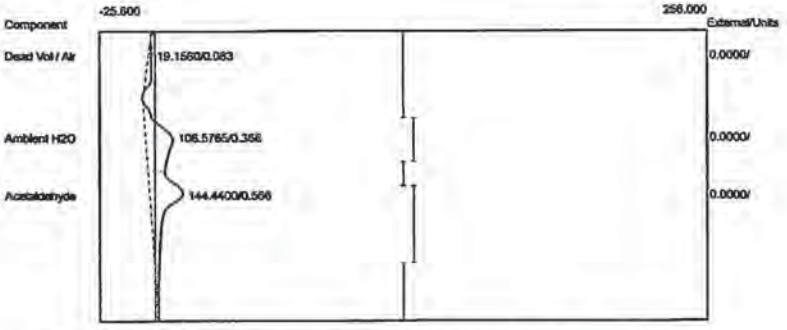
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.4195	0.0000	
Ambient H2O	0.366	113.7985	0.0000	
Acetaldehyde	0.550	168.7720	0.0000	
		299.9900	0.0000	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:13:03
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A10.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



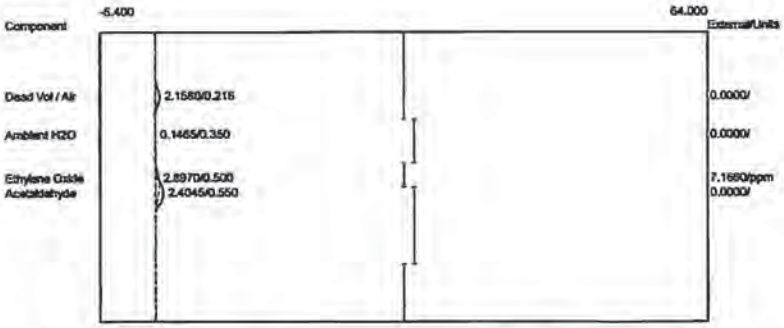
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.2400	0.0000	
Ambient H2O	0.366	0.1260	0.0000	
Ethylene Oxide	0.500	2.4520	6.0653	ppm
Acetaldehyde	0.566	3.0910	0.0000	
		7.9090	6.0653	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:13:03
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A10.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



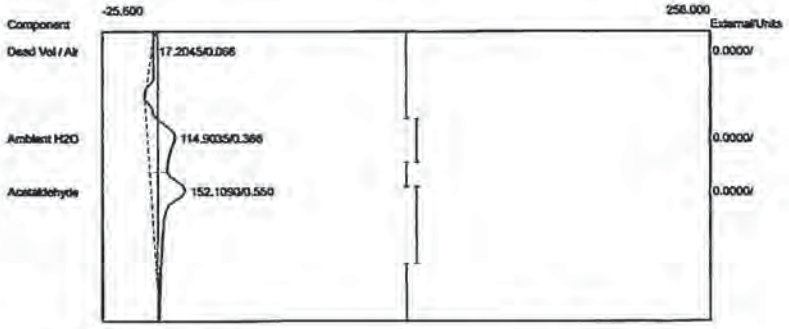
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	19.1580	0.0000	
Ambient H2O	0.366	106.5765	0.0000	
Acetaldehyde	0.566	144.4400	0.0000	
		270.1745	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:08:03
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A09.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



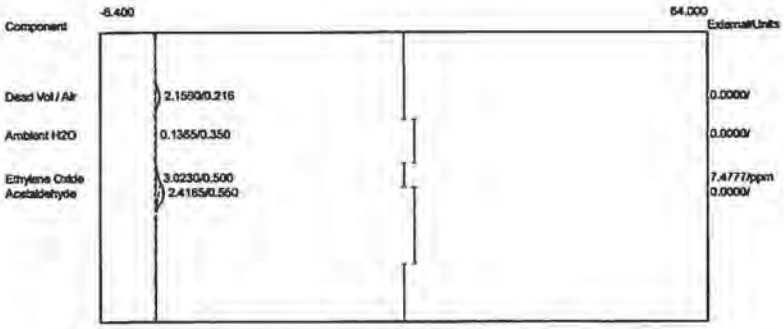
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1580	0.0000	
Ambient H2O	0.350	0.1465	0.0000	
Ethylene Oxide	0.500	2.8970	7.1660	ppm
Acetaldehyde	0.550	2.4045	0.0000	
		7.6060	7.1660	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:08:03
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A09.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



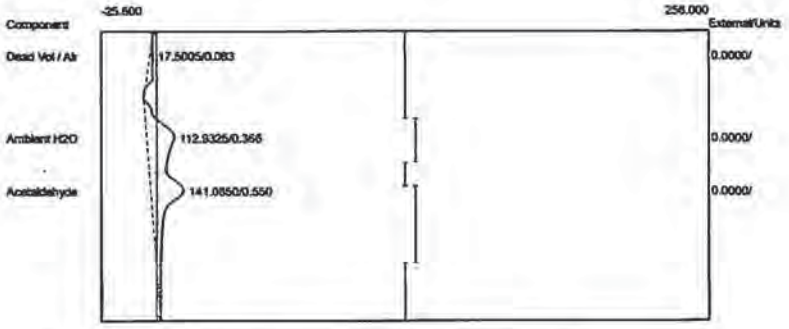
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.2045	0.0000	
Ambient H2O	0.366	114.9035	0.0000	
Acetaldehyde	0.550	152.1090	0.0000	
		284.2170	0.0000	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:03:36
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A08.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



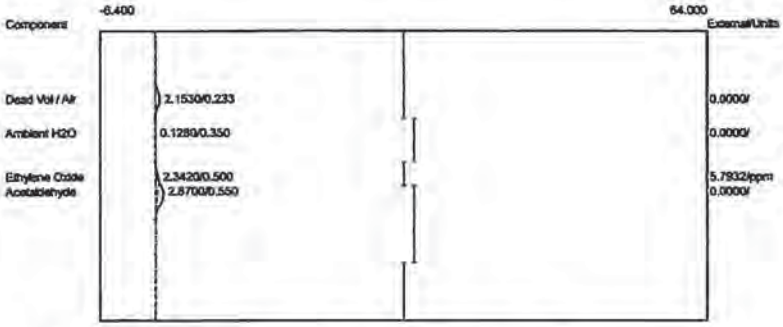
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1590	0.0000	
Ambient H2O	0.350	0.1365	0.0000	
Ethylene Oxide	0.500	3.0230	7.4777	ppm
Acetaldehyde	0.550	2.4185	0.0000	
		7.7370	7.4777	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:03:36
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A08.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



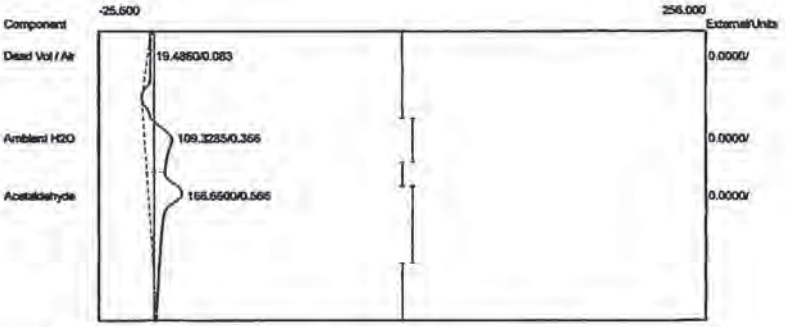
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	17.5005	0.0000	
Ambient H2O	0.366	112.9325	0.0000	
Acetaldehyde	0.550	141.0850	0.0000	
		271.5180	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:58:29
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A07.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



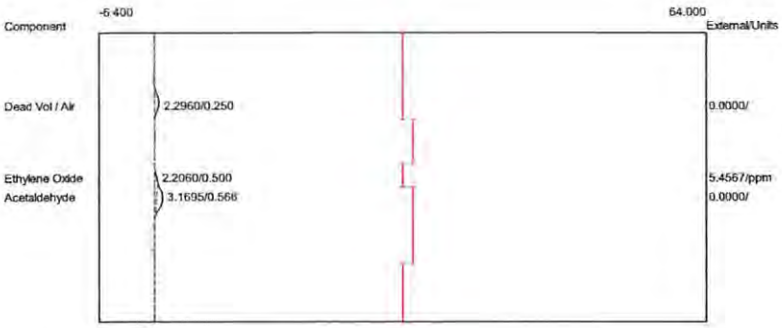
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1530	0.0000	
Ambient H2O	0.350	0.1280	0.0000	
Ethylene Oxide	0.500	2.3420	5.7932	ppm
Acetaldehyde	0.550	2.8700	0.0000	
		7.4930	5.7932	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:58:29
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A07.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



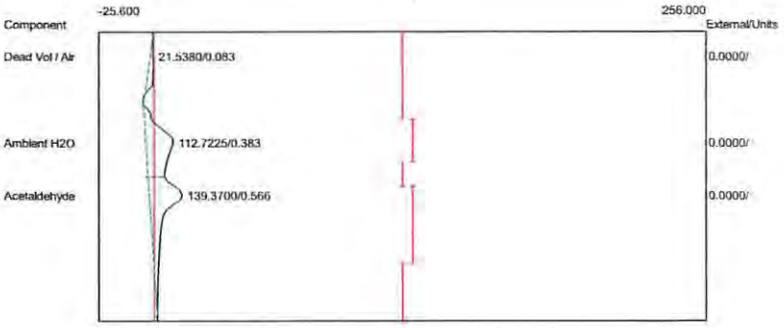
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	19.4860	0.0000	
Ambient H2O	0.366	109.3285	0.0000	
Acetaldehyde	0.566	166.6600	0.0000	
		295.4745	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:53:06
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A06.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



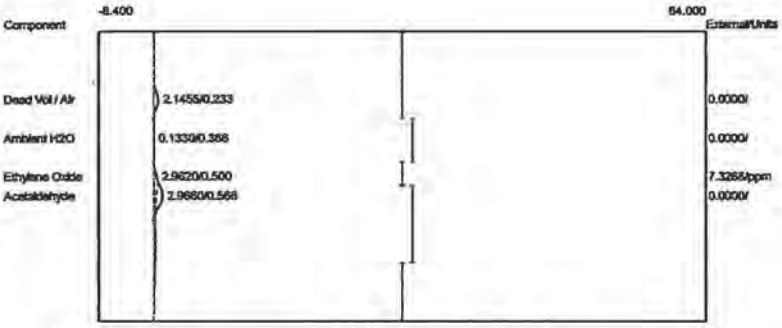
Component	Retention	Area	External	Units
Dead Vol / Air	0.250	2.2960	0.0000	
Ethylene Oxide	0.500	2.2060	5.4567	ppm
Acetaldehyde	0.566	3.1695	0.0000	
		7.6715	5.4567	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:53:06
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A06.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



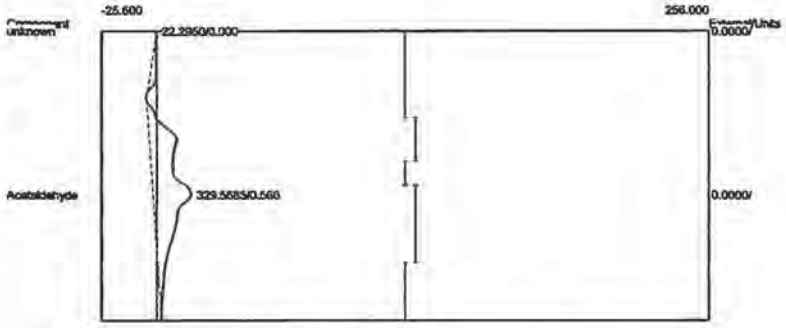
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.5380	0.0000	
Ambient H2O	0.383	112.7225	0.0000	
Acetaldehyde	0.566	139.3700	0.0000	
		273.6305	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:48:40
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A05.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



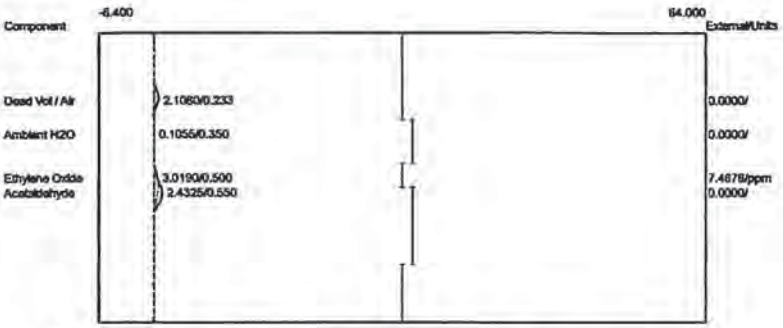
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1455	0.0000	
Ambient H2O	0.366	0.1330	0.0000	
Ethylene Oxide	0.500	2.9620	7.3268	ppm
Acetaldehyde	0.566	2.9660	0.0000	
		8.2065	7.3268	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:48:40
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A05.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



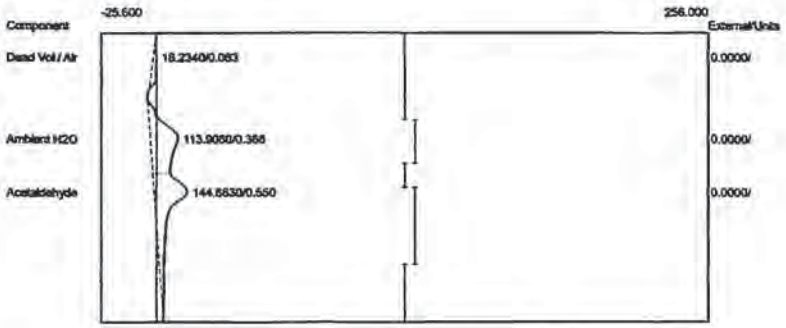
Component	Retention	Area	External	Units
Acetaldehyde	0.566	329.5685	0.0000	
		329.5685	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:43:12
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A04.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



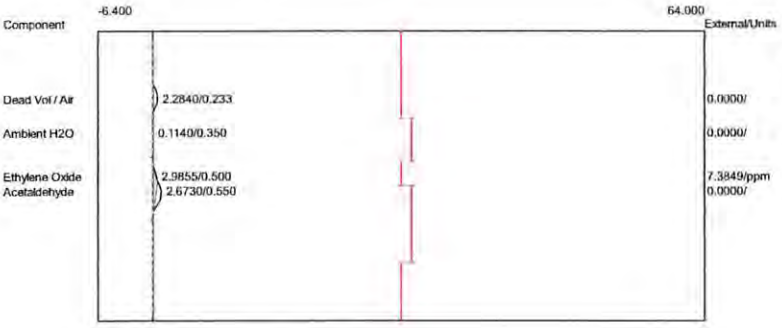
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1080	0.0000	
Ambient H2O	0.350	0.1055	0.0000	
Ethylene Oxide	0.500	3.0190	7.4678	ppm
Acetaldehyde	0.550	2.4325	0.0000	
		7.6650	7.4678	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:43:12
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A04.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



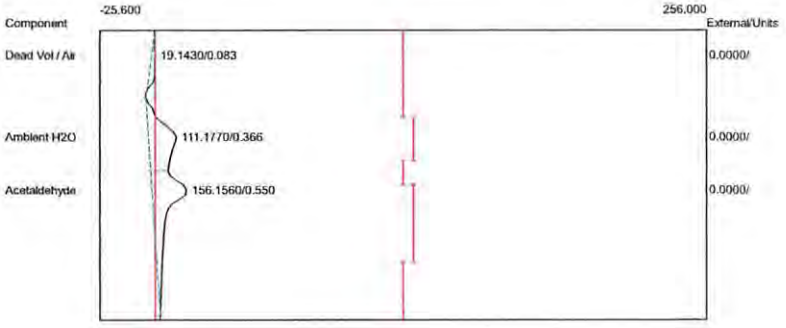
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	18.2340	0.0000	
Ambient H2O	0.366	113.9080	0.0000	
Acetaldehyde	0.550	144.8630	0.0000	
		277.0050	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:38:07
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A03.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.2840	0.0000	
Ambient H2O	0.350	0.1140	0.0000	
Ethylene Oxide	0.500	2.9855	7.3849	ppm
Acetaldehyde	0.550	2.6730	0.0000	
		8.0565	7.3849	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:38:07
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A03.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer

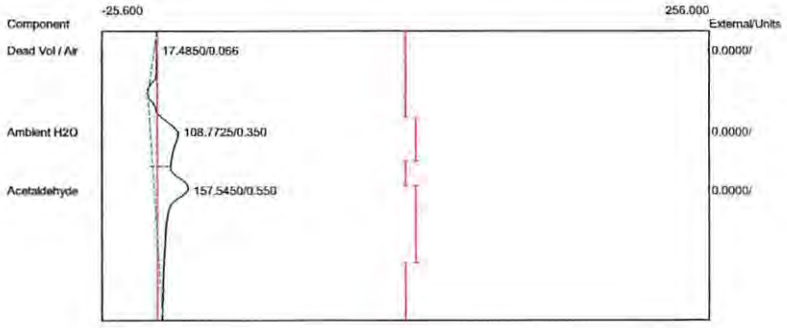


Component	Retention	Area	External	Units
Dead Vol / Air	0.083	19.1430	0.0000	
Ambient H2O	0.366	111.1770	0.0000	
Acetaldehyde	0.550	156.1560	0.0000	
		286.4760	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:33:38
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A02.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer

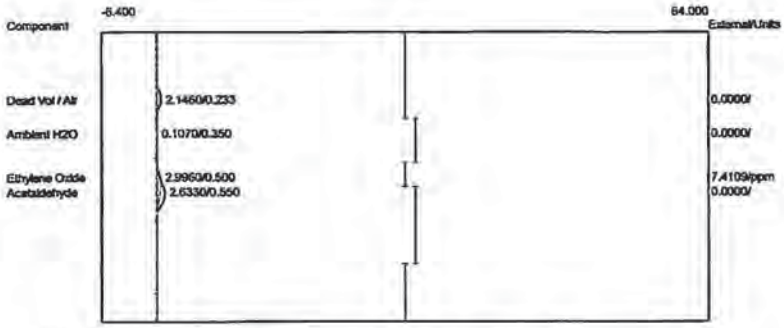
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.2170	0.0000	
Ambient H2O	0.350	0.1350	0.0000	
Ethylene Oxide	0.483	2.7530	6.8098	ppm
Acetaldehyde	0.533	2.9880	0.0000	
		8.0930	6.8098	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:33:38
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A02.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



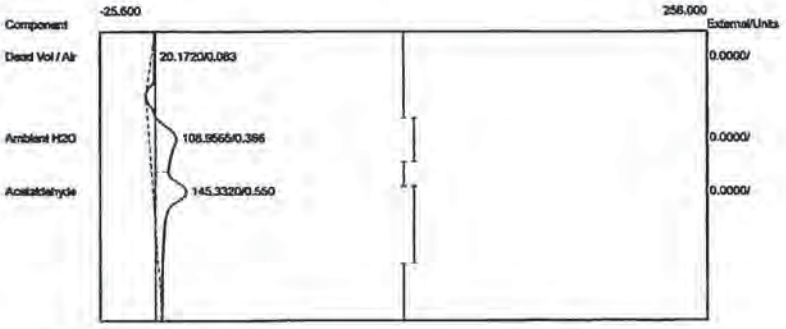
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.4850	0.0000	
Ambient H2O	0.350	108.7725	0.0000	
Acetaldehyde	0.550	157.5450	0.0000	
		283.8025	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:28:42
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A01.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



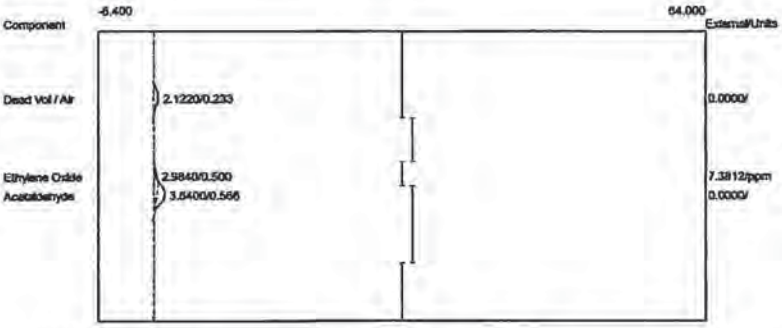
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1460	0.0000	
Ambient H2O	0.350	0.1070	0.0000	
Ethylene Oxide	0.500	2.9960	7.4109	ppm
Acetaldehyde	0.550	2.6330	0.0000	
		7.8820	7.4109	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:28:42
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A01.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



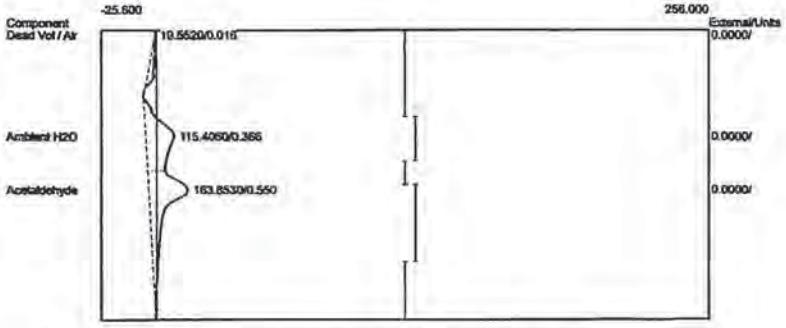
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	20.1720	0.0000	
Ambient H2O	0.366	108.9565	0.0000	
Acetaldehyde	0.550	145.3320	0.0000	
		274.4605	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 14:23:19
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A12.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



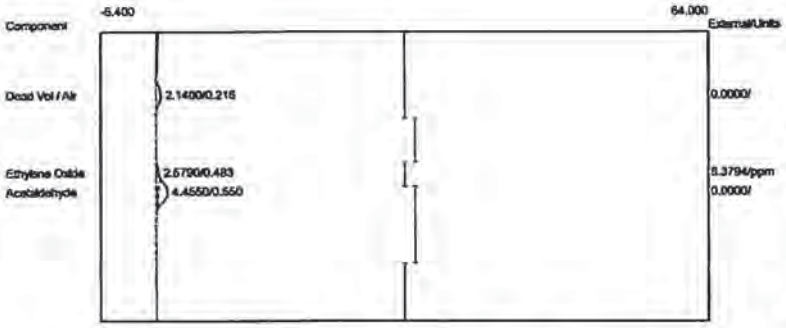
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1220	0.0000	
Ethylene Oxide	0.500	2.9840	7.3812	ppm
Acetaldehyde	0.566	3.8400	0.0000	
		8.9460	7.3812	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 14:23:19
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A12.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



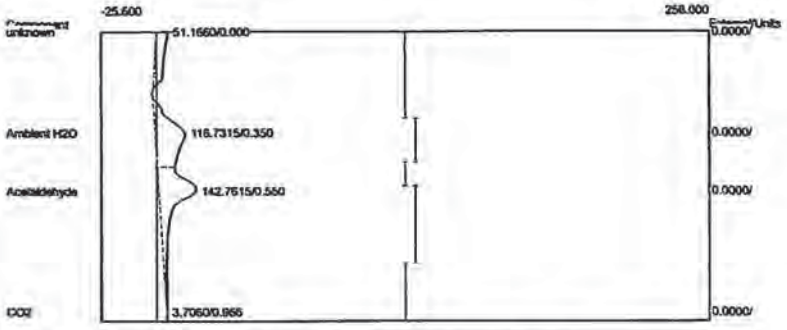
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	19.5520	0.0000	
Ambient H2O	0.366	115.4060	0.0000	
Acetaldehyde	0.550	163.8530	0.0000	
		298.8110	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 14:18:23
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A11.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



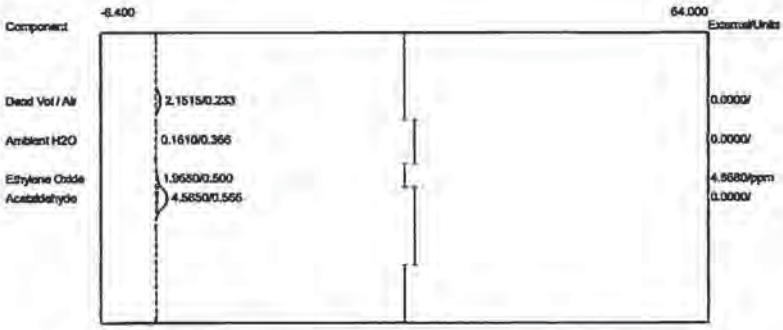
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1400	0.0000	
Ethylene Oxide	0.483	2.5790	6.3794	ppm
Acetaldehyde	0.550	4.4550	0.0000	
		9.1740	6.3794	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 14:18:23
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A11.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



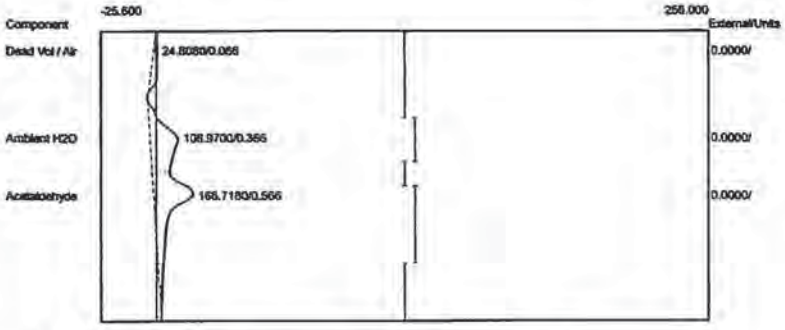
Component	Retention	Area	External	Units
Ambient H2O	0.350	116.7315	0.0000	
Acetaldehyde	0.550	142.7615	0.0000	
CO2	0.966	3.7060	0.0000	
		263.1990	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 14:13:06
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A10.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



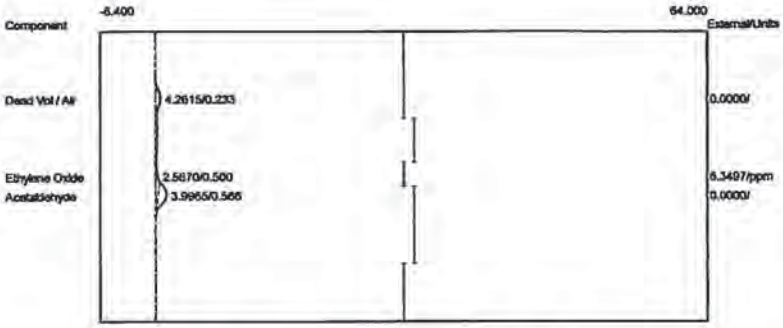
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1515	0.0000	
Ambient H2O	0.366	0.1610	0.0000	
Ethylene Oxide	0.500	1.9680	4.8680	ppm
Acetaldehyde	0.566	4.5850	0.0000	
		8.8655	4.8680	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 14:13:06
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A10.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



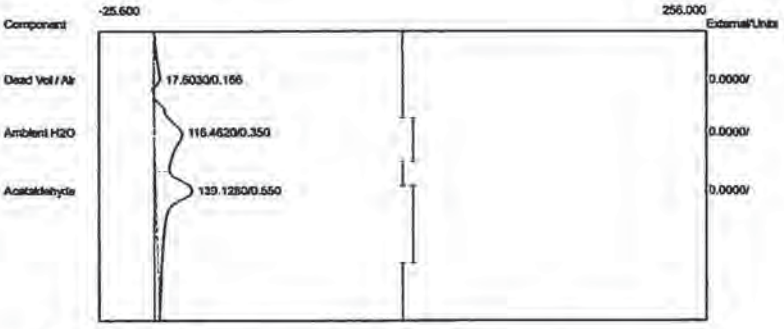
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	24.8080	0.0000	
Ambient H2O	0.366	108.9700	0.0000	
Acetaldehyde	0.566	166.7180	0.0000	
		300.4960	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 14:08:20
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A09.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



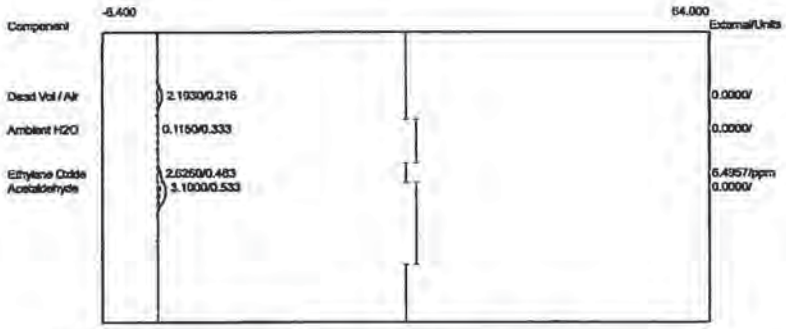
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	4.2615	0.0000	
Ethylene Oxide	0.500	2.5670	6.3497	ppm
Acetaldehyde	0.566	3.9965	0.0000	
		10.8250	6.3497	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 14:08:20
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A09.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



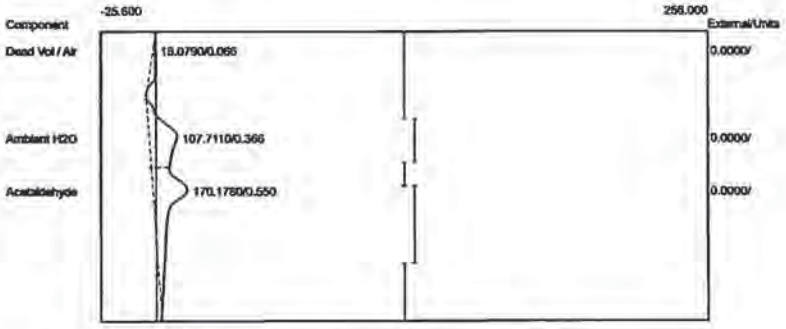
Component	Retention	Area	External	Units
Dead Vol / Air	0.166	17.6030	0.0000	
Ambient H2O	0.350	116.4620	0.0000	
Acetaldehyde	0.550	139.1280	0.0000	
		273.1930	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:23:39
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A12.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



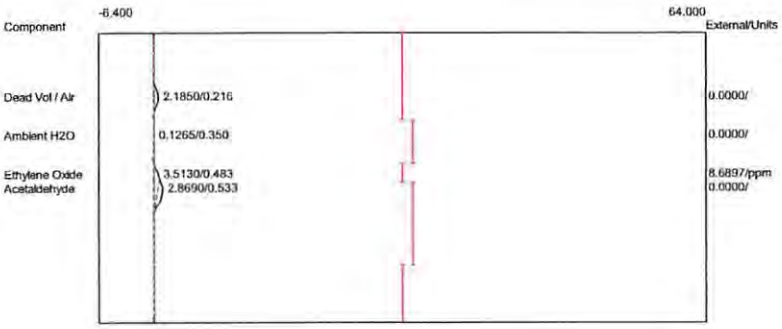
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1930	0.0000	
Ambient H2O	0.333	0.1150	0.0000	
Ethylene Oxide	0.483	2.6260	6.4957	ppm
Acetaldehyde	0.533	3.1000	0.0000	
		8.0340	6.4957	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:23:39
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A12.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



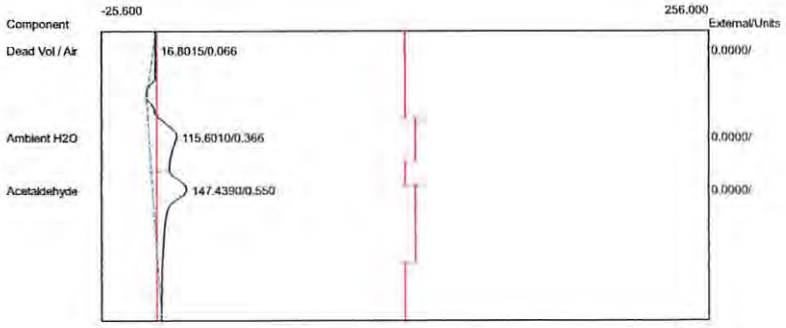
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	18.0790	0.0000	
Ambient H2O	0.366	107.7110	0.0000	
Acetaldehyde	0.550	170.1780	0.0000	
		295.9680	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:18:19
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A11.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



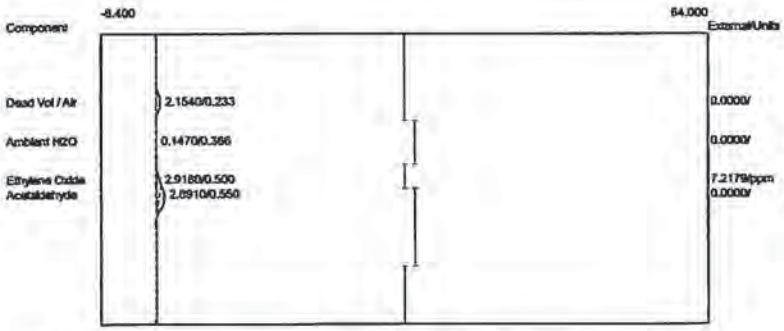
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1850	0.0000	
Ambient H2O	0.350	0.1265	0.0000	
Ethylene Oxide	0.483	3.5130	8.6897	ppm
Acetaldehyde	0.533	2.8690	0.0000	
		8.6935	8.6897	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:18:19
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A11.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



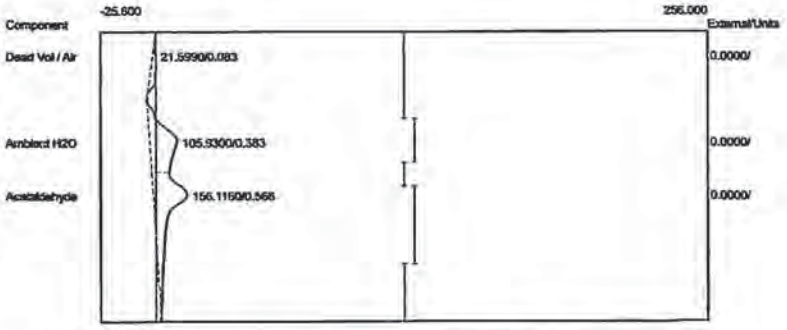
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	16.8015	0.0000	
Ambient H2O	0.366	115.6010	0.0000	
Acetaldehyde	0.550	147.4390	0.0000	
		279.8415	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:13:18
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A10.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



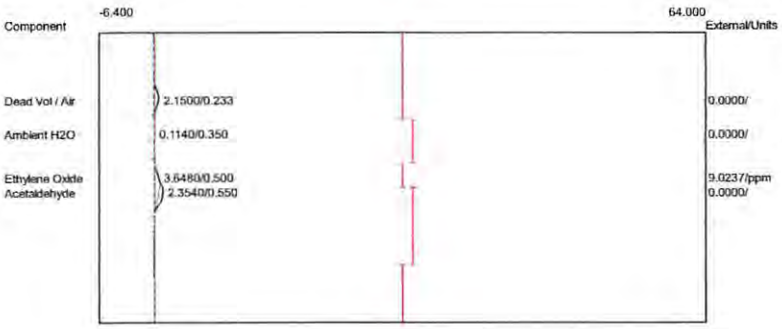
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1540	0.0000	
Ambient H2O	0.366	0.1470	0.0000	
Ethylene Oxide	0.500	2.9180	7.2179	ppm
Acetaldehyde	0.550	2.8910	0.0000	
		8.1100	7.2179	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:13:18
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A10.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



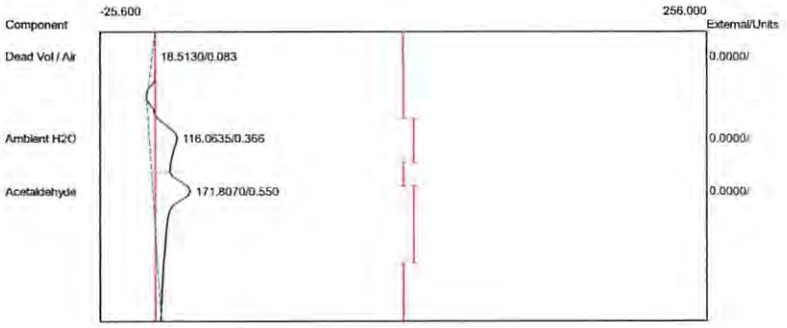
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.5990	0.0000	
Ambient H2O	0.383	105.9300	0.0000	
Acetaldehyde	0.566	156.1160	0.0000	
		283.6450	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:08:33
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A09.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



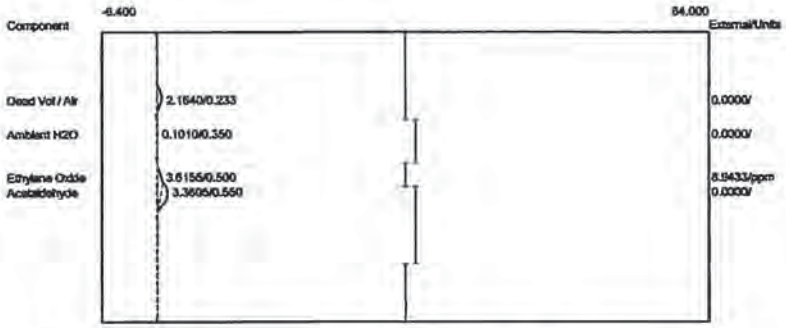
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1500	0.0000	
Ambient H2O	0.350	0.1140	0.0000	
Ethylene Oxide	0.500	3.6480	9.0237	ppm
Acetaldehyde	0.550	2.3540	0.0000	
		8.2660	9.0237	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:08:33
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A09.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



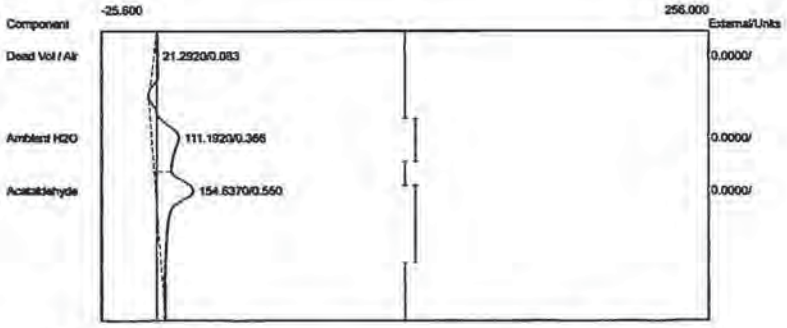
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	18.5130	0.0000	
Ambient H2O	0.366	116.0635	0.0000	
Acetaldehyde	0.550	171.8070	0.0000	
		306.3835	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 12:03:07
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A08.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



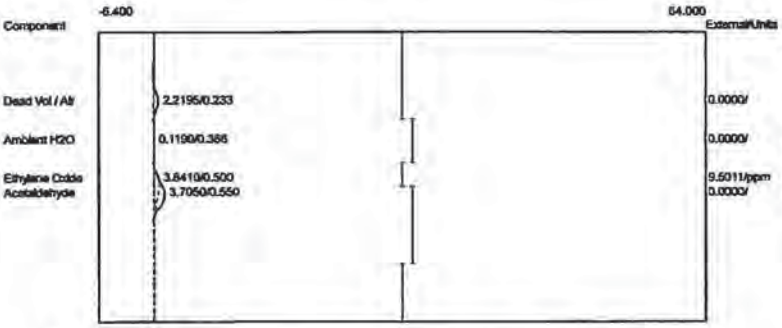
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1640	0.0000	
Ambient H2O	0.350	0.1010	0.0000	
Ethylene Oxide	0.500	3.6155	8.9433	ppm
Acetaldehyde	0.550	3.3605	0.0000	
		9.2410	8.9433	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 12:03:07
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A08.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



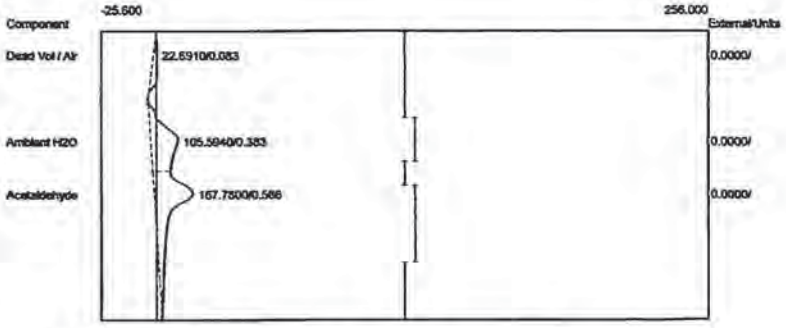
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.2920	0.0000	
Ambient H2O	0.366	111.1920	0.0000	
Acetaldehyde	0.550	154.6370	0.0000	
		287.1210	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:58:06
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A07.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



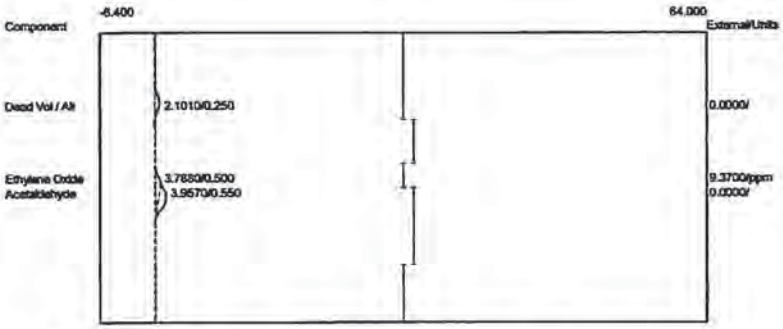
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.2195	0.0000	
Ambient H2O	0.366	0.1190	0.0000	
Ethylene Oxide	0.500	3.8410	9.5011	ppm
Acetaldehyde	0.550	3.7050	0.0000	
		9.8845	9.5011	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:58:06
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A07.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



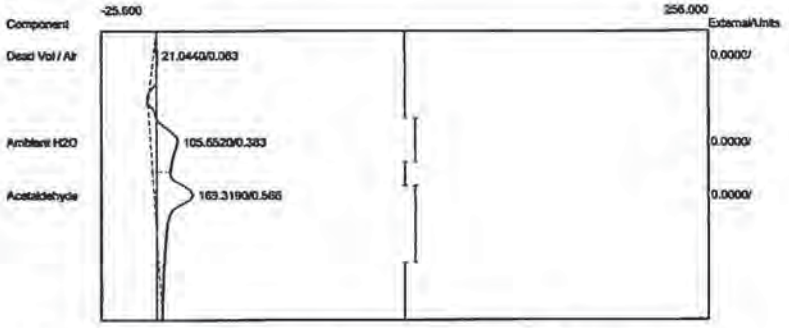
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	22.6910	0.0000	
Ambient H2O	0.383	105.5940	0.0000	
Acetaldehyde	0.566	167.7800	0.0000	
		296.0650	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:53:36
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A06.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



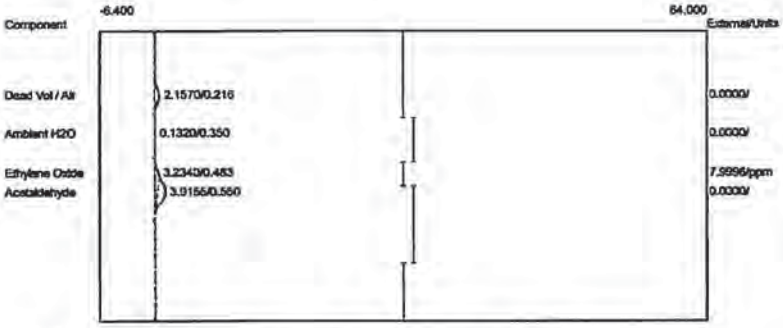
Component	Retention	Area	External	Units
Dead Vol / Air	0.250	2.1010	0.0000	
Ethylene Oxide	0.500	3.7880	9.3700	ppm
Acetaldehyde	0.550	3.9570	0.0000	
		9.8460	9.3700	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:53:36
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A06.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



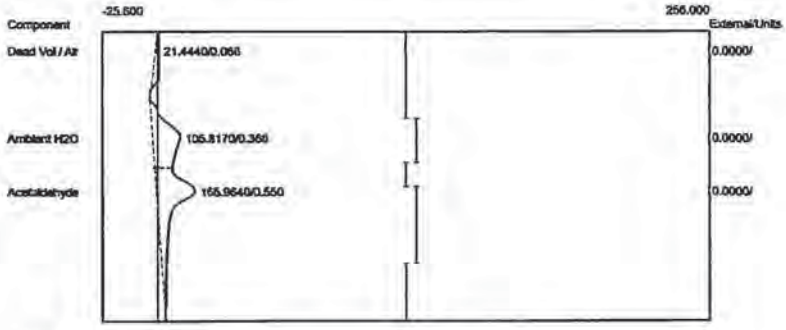
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.0440	0.0000	
Ambient H2O	0.383	105.6520	0.0000	
Acetaldehyde	0.566	169.3190	0.0000	
		296.0150	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:48:44
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A05.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



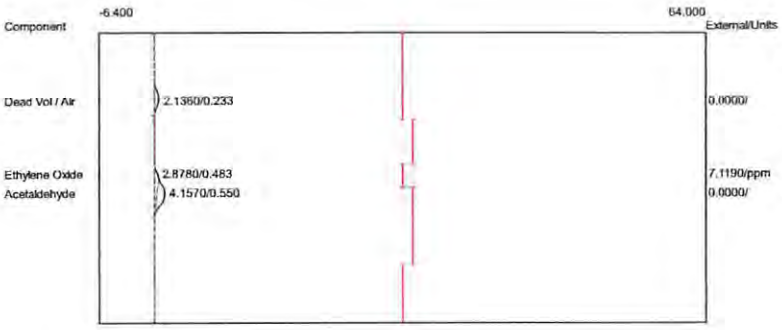
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1570	0.0000	
Ambient H2O	0.350	0.1320	0.0000	
Ethylene Oxide	0.483	3.2340	7.9996	ppm
Acetaldehyde	0.550	3.9155	0.0000	
		9.4385	7.9996	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:48:44
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A05.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



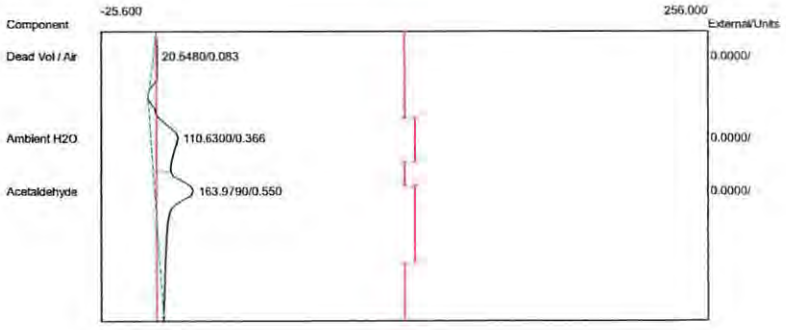
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	21.4440	0.0000	
Ambient H2O	0.366	105.8170	0.0000	
Acetaldehyde	0.550	165.9640	0.0000	
		293.2250	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:43:37
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A04.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



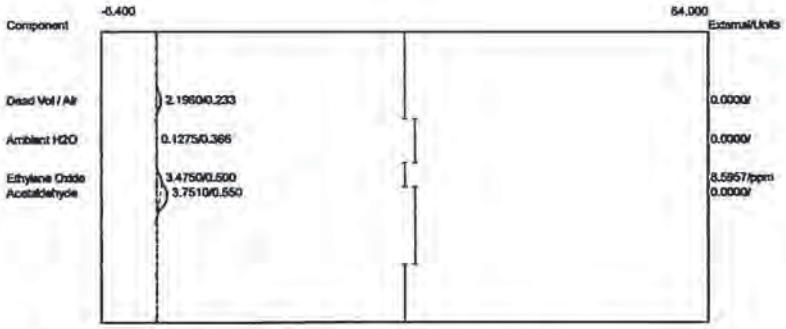
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1360	0.0000	
Ethylene Oxide	0.483	2.8780	7.1190	ppm
Acetaldehyde	0.550	4.1570	0.0000	
		9.1710	7.1190	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:43:37
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A04.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



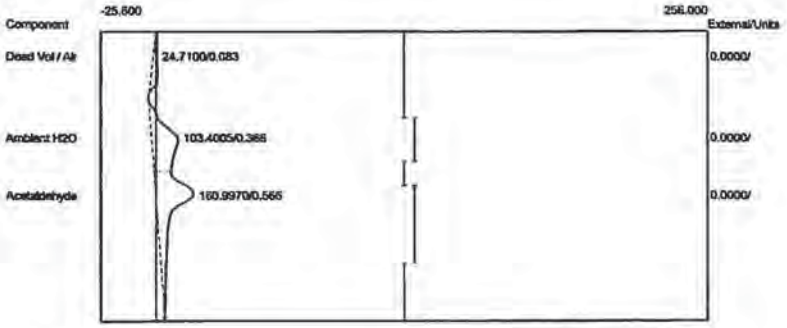
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	20.5480	0.0000	
Ambient H2O	0.366	110.6300	0.0000	
Acetaldehyde	0.550	163.9790	0.0000	
		295.1570	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:38:22
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A03.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



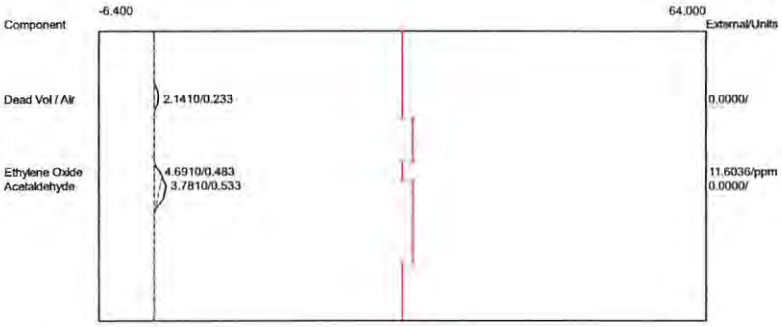
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1960	0.0000	
Ambient H2O	0.366	0.1275	0.0000	
Ethylene Oxide	0.500	3.4750	8.5957	ppm
Acetaldehyde	0.550	3.7510	0.0000	
		9.5495	8.5957	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:38:22
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A03.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



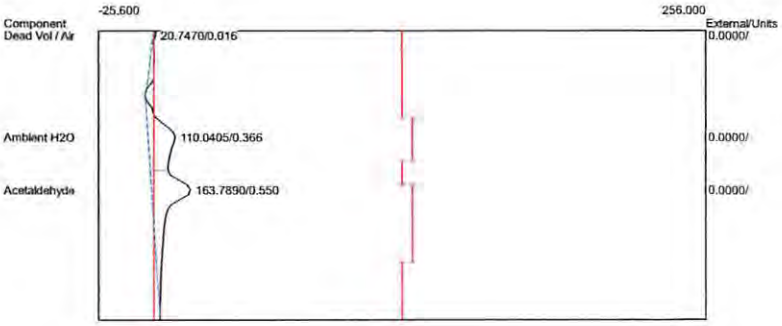
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	24.7100	0.0000	
Ambient H2O	0.366	103.4005	0.0000	
Acetaldehyde	0.566	160.9970	0.0000	
		289.1075	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:33:13
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A02.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



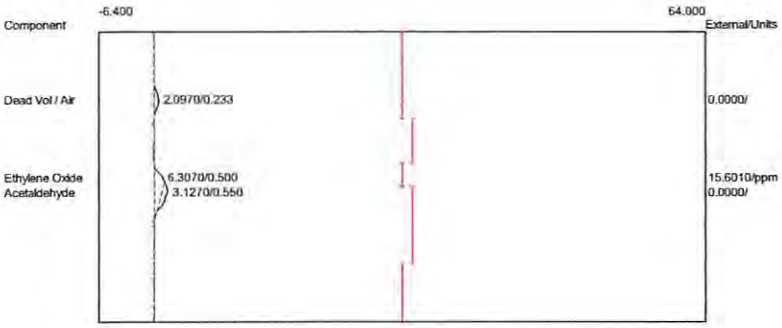
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1410	0.0000	
Ethylene Oxide	0.483	4.6910	11.6036	ppm
Acetaldehyde	0.533	3.7810	0.0000	
		10.6130	11.6036	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:33:13
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A02.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



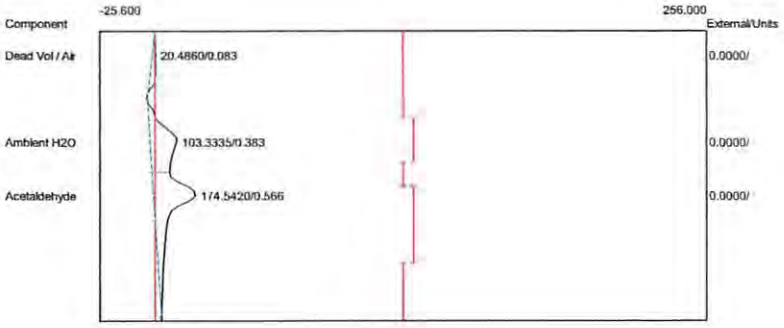
Component	Retention	Area	External	Units
Dead Vol / Air	0.016	20.7470	0.0000	
Ambient H2O	0.366	110.0405	0.0000	
Acetaldehyde	0.550	163.7890	0.0000	
		294.5765	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/27/2018 11:28:16
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-1A01.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



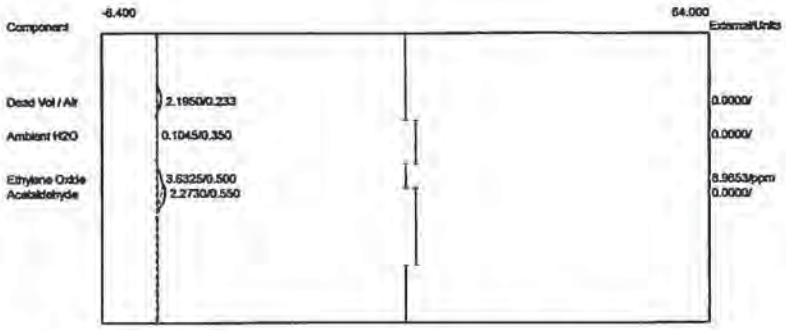
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.0970	0.0000	
Ethylene Oxide	0.500	6.3070	15.6010	ppm
Acetaldehyde	0.550	3.1270	0.0000	
		11.5310	15.6010	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#1Aer
Analysis date: 07/28/2018 11:28:16
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-1A01.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



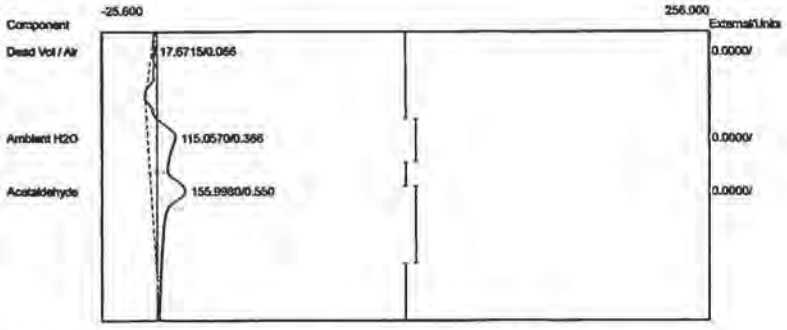
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	20.4860	0.0000	
Ambient H2O	0.383	103.3335	0.0000	
Acetaldehyde	0.566	174.5420	0.0000	
		298.3615	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:23:13
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A12.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



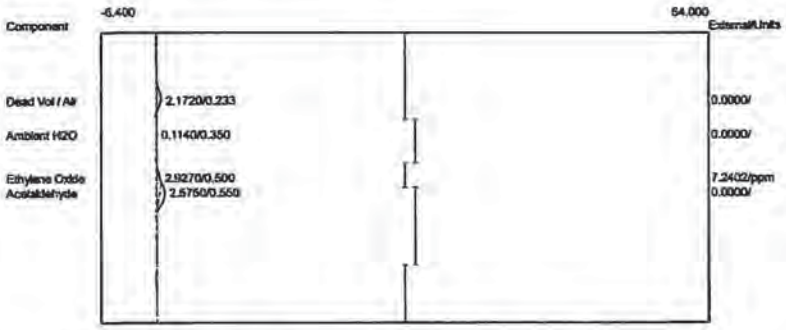
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1950	0.0000	
Ambient H2O	0.350	0.1045	0.0000	
Ethylene Oxide	0.500	3.6325	8.9853	ppm
Acetaldehyde	0.550	2.2730	0.0000	
		8.2050	8.9853	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:23:13
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A12.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



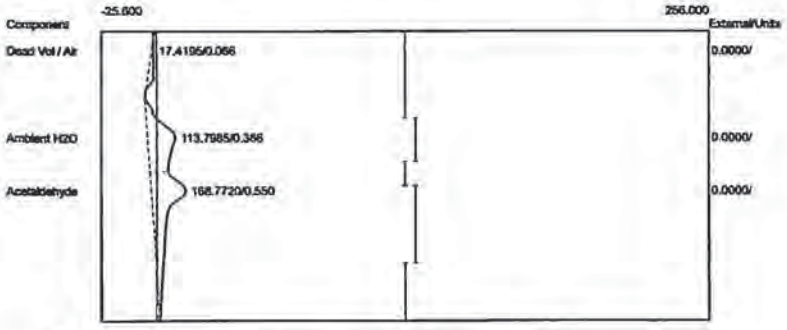
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.6715	0.0000	
Ambient H2O	0.366	115.0570	0.0000	
Acetaldehyde	0.550	155.9980	0.0000	
		288.7265	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:18:26
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A11.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



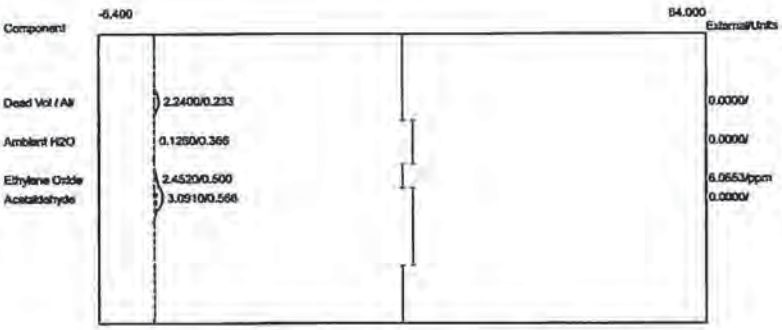
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1720	0.0000	
Ambient H2O	0.350	0.1140	0.0000	
Ethylene Oxide	0.500	2.9270	7.2402	ppm
Acetaldehyde	0.550	2.5750	0.0000	
		7.7880	7.2402	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:18:26
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A11.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



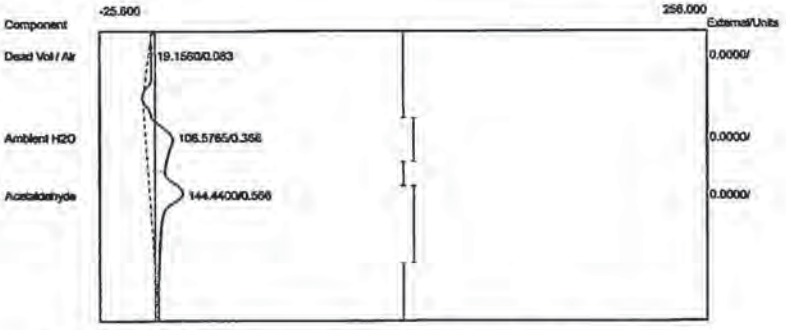
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.4195	0.0000	
Ambient H2O	0.366	113.7985	0.0000	
Acetaldehyde	0.550	168.7720	0.0000	
		299.9900	0.0000	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:13:03
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A10.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



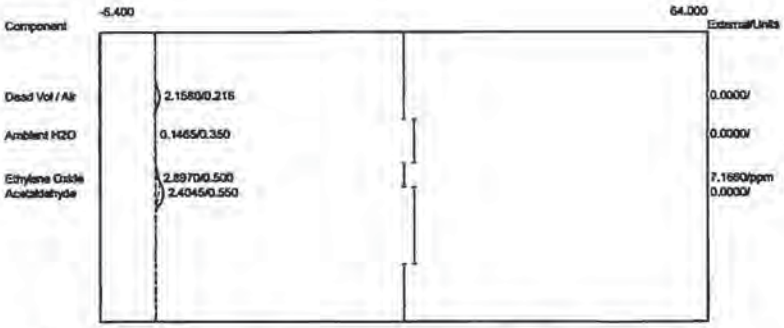
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.2400	0.0000	
Ambient H2O	0.366	0.1260	0.0000	
Ethylene Oxide	0.500	2.4520	6.0653	ppm
Acetaldehyde	0.566	3.0910	0.0000	
		7.9090	6.0653	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:13:03
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A10.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



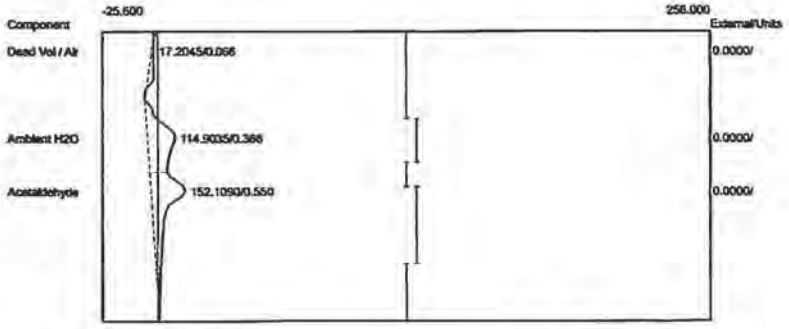
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	19.1580	0.0000	
Ambient H2O	0.366	106.5765	0.0000	
Acetaldehyde	0.566	144.4400	0.0000	
		270.1745	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:08:03
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A09.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



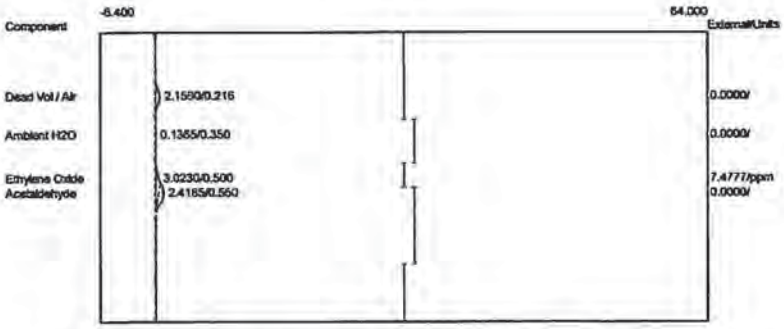
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1580	0.0000	
Ambient H2O	0.350	0.1465	0.0000	
Ethylene Oxide	0.500	2.8970	7.1660	ppm
Acetaldehyde	0.550	2.4045	0.0000	
		7.6060	7.1660	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:08:03
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A09.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



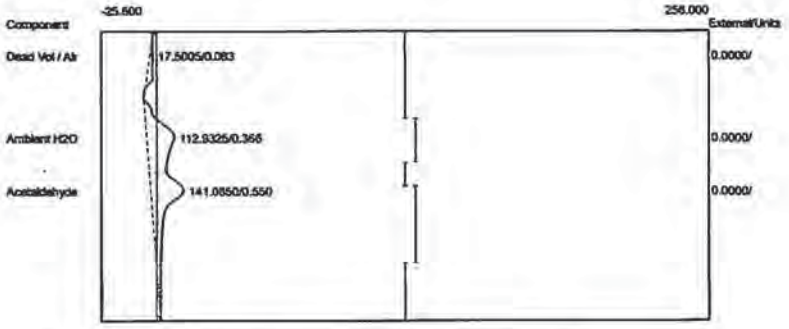
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.2045	0.0000	
Ambient H2O	0.366	114.9035	0.0000	
Acetaldehyde	0.550	152.1090	0.0000	
		284.2170	0.0000	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 13:03:36
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A08.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



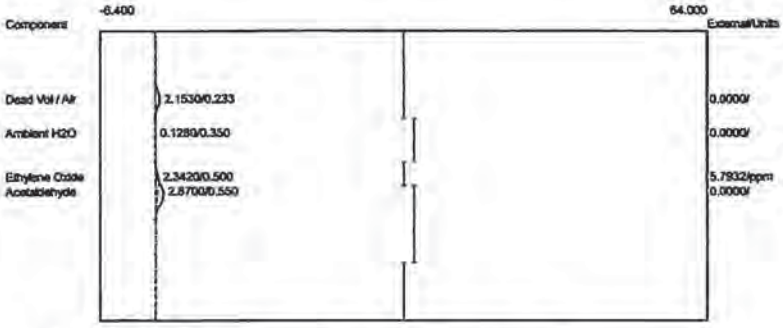
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1590	0.0000	
Ambient H2O	0.350	0.1365	0.0000	
Ethylene Oxide	0.500	3.0230	7.4777	ppm
Acetaldehyde	0.550	2.4185	0.0000	
		7.7370	7.4777	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 13:03:36
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A08.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



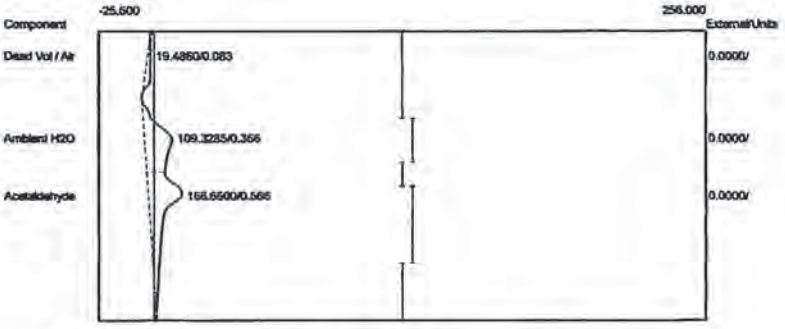
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	17.5005	0.0000	
Ambient H2O	0.366	112.9325	0.0000	
Acetaldehyde	0.550	141.0850	0.0000	
		271.5180	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:58:29
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A07.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



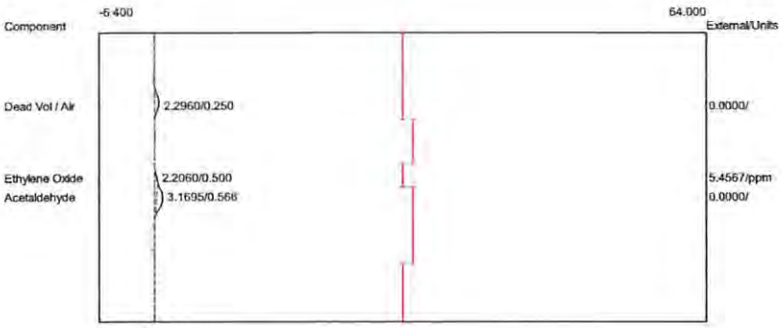
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1530	0.0000	
Ambient H2O	0.350	0.1280	0.0000	
Ethylene Oxide	0.500	2.3420	5.7932	ppm
Acetaldehyde	0.550	2.8700	0.0000	
		7.4930	5.7932	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:58:29
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A07.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



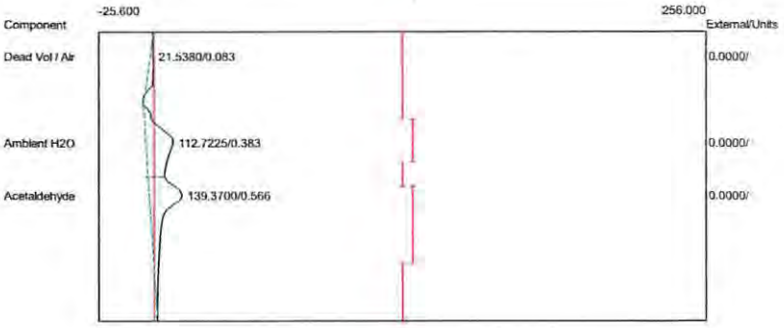
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	19.4860	0.0000	
Ambient H2O	0.366	109.3285	0.0000	
Acetaldehyde	0.566	166.6600	0.0000	
		295.4745	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:53:06
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A06.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



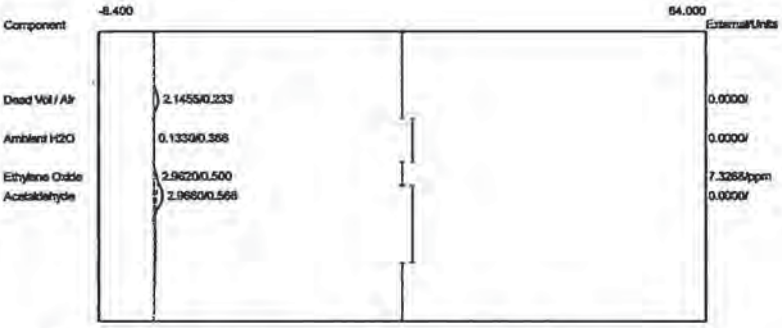
Component	Retention	Area	External	Units
Dead Vol / Air	0.250	2.2960	0.0000	
Ethylene Oxide	0.500	2.2060	5.4567	ppm
Acetaldehyde	0.566	3.1695	0.0000	
		7.6715	5.4567	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:53:06
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A06.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



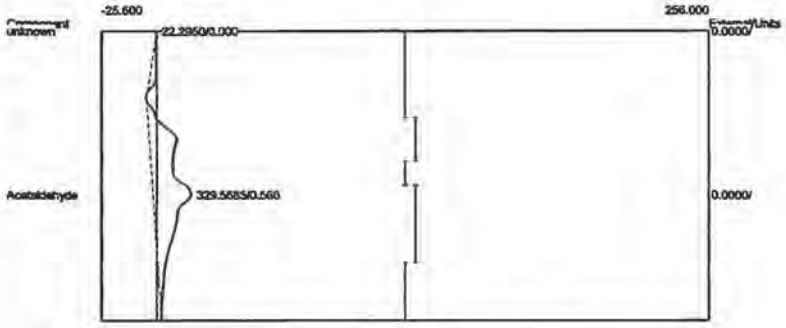
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	21.5380	0.0000	
Ambient H2O	0.383	112.7225	0.0000	
Acetaldehyde	0.566	139.3700	0.0000	
		273.6305	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/27/2018 12:48:40
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-2A05.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



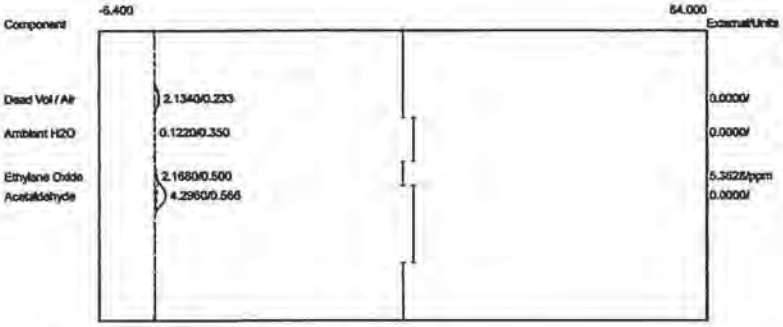
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1455	0.0000	
Ambient H2O	0.366	0.1330	0.0000	
Ethylene Oxide	0.500	2.9620	7.3268	ppm
Acetaldehyde	0.566	2.9660	0.0000	
		8.2065	7.3268	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#2Aer
Analysis date: 07/28/2018 12:48:40
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-2A05.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



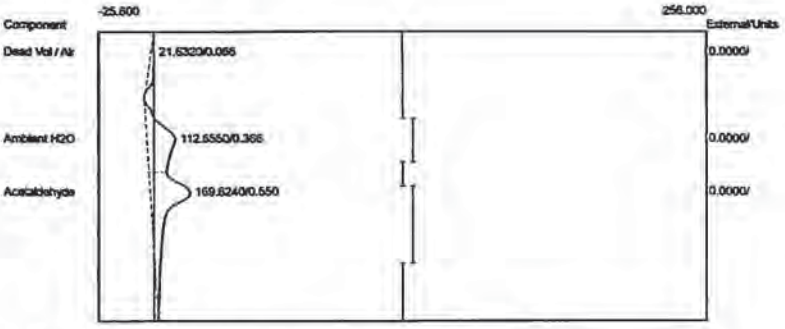
Component	Retention	Area	External	Units
Acetaldehyde	0.566	329.5685	0.0000	
		329.5685	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 14:03:11
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A08.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



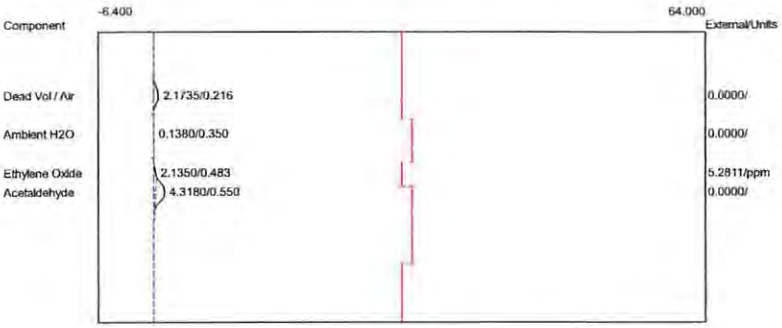
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1340	0.0000	
Ambient H2O	0.350	0.1220	0.0000	
Ethylene Oxide	0.500	2.1680	5.3628	ppm
Acetaldehyde	0.566	4.2960	0.0000	
		8.7200	5.3628	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 14:03:11
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A08.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



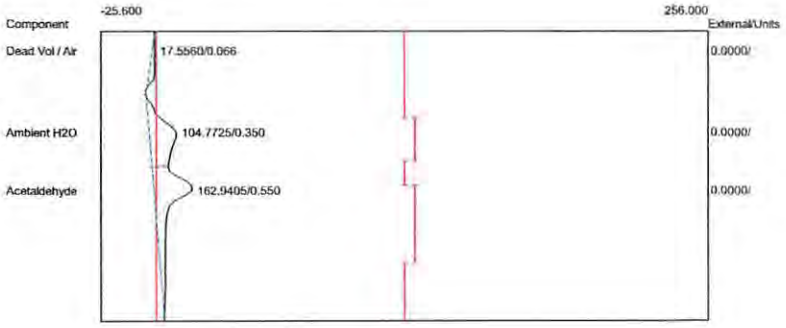
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	21.6320	0.0000	
Ambient H2O	0.366	112.6550	0.0000	
Acetaldehyde	0.550	169.6240	0.0000	
		303.9110	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 13:58:28
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A07.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



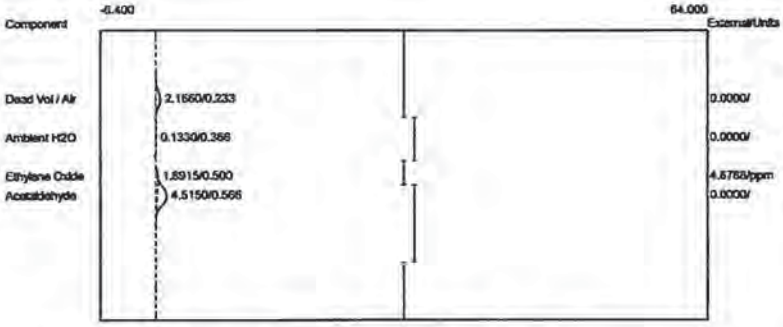
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1735	0.0000	
Ambient H2O	0.350	0.1380	0.0000	
Ethylene Oxide	0.483	2.1350	5.2811	ppm
Acetaldehyde	0.550	4.3180	0.0000	
		8.7645	5.2811	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 13:58:28
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A07.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



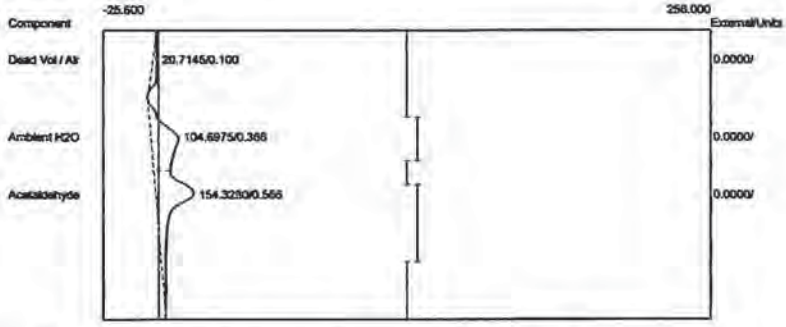
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.5560	0.0000	
Ambient H2O	0.350	104.7725	0.0000	
Acetaldehyde	0.550	162.9405	0.0000	
		285.2690	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 13:53:20
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A06.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



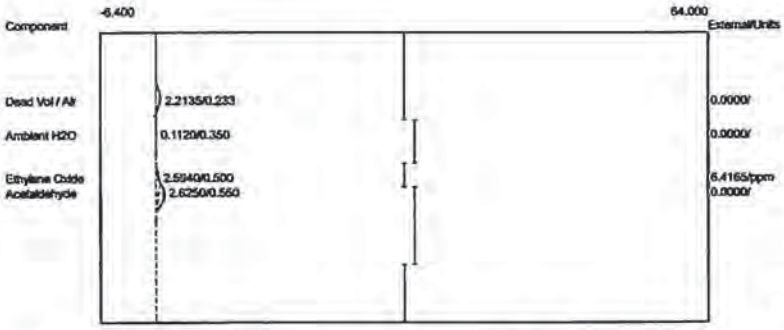
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1660	0.0000	
Ambient H2O	0.366	0.1330	0.0000	
Ethylene Oxide	0.500	1.8915	4.6788	ppm
Acetaldehyde	0.566	4.5150	0.0000	
		8.7055	4.6788	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 13:53:20
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A06.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



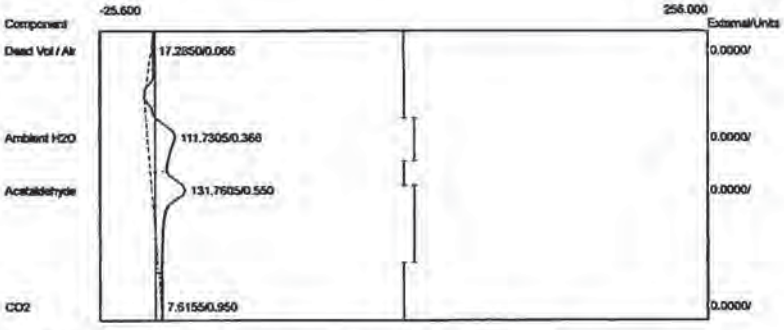
Component	Retention	Area	External	Units
Dead Vol / Air	0.100	20.7145	0.0000	
Ambient H2O	0.366	104.6975	0.0000	
Acetaldehyde	0.566	154.3280	0.0000	
		279.7400	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 13:48:12
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A05.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



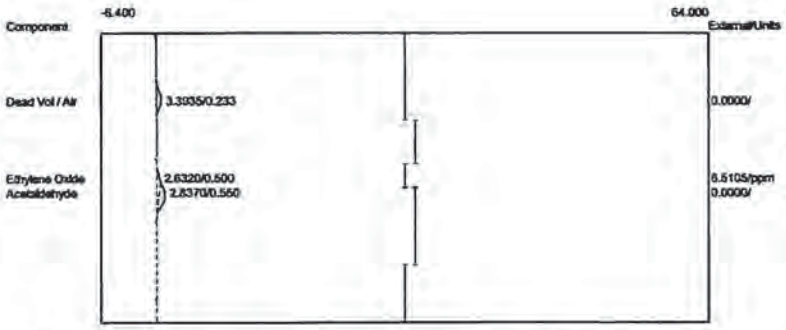
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.2135	0.0000	
Ambient H2O	0.350	0.1120	0.0000	
Ethylene Oxide	0.500	2.5940	6.4165	ppm
Acetaldehyde	0.550	2.6250	0.0000	
		7.5445	6.4165	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 13:48:12
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A05.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



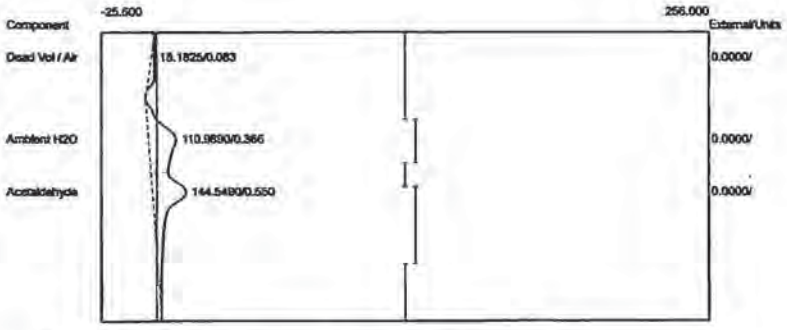
Component	Retention	Area	External	Units
Dead Vol / Air	0.066	17.2850	0.0000	
Ambient H2O	0.366	111.7305	0.0000	
Acetaldehyde	0.550	131.7605	0.0000	
CO2	0.950	7.6155	0.0000	
		268.3915	0.0000	

Lab name: ECSI
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 13:43:08
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A04.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



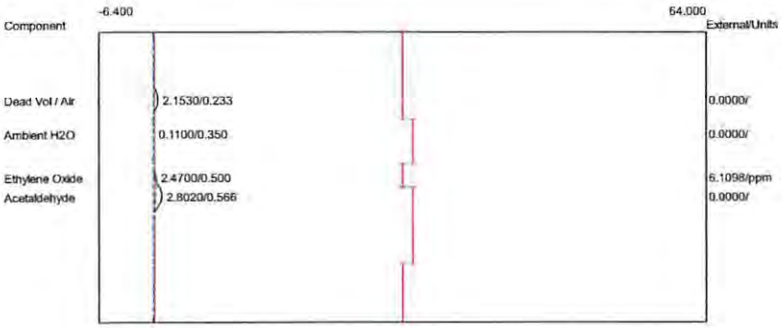
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	3.3935	0.0000	
Ethylene Oxide	0.500	2.6320	6.5105	ppm
Acetaldehyde	0.550	2.8370	0.0000	
		8.8625	6.5105	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 13:43:08
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A04.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



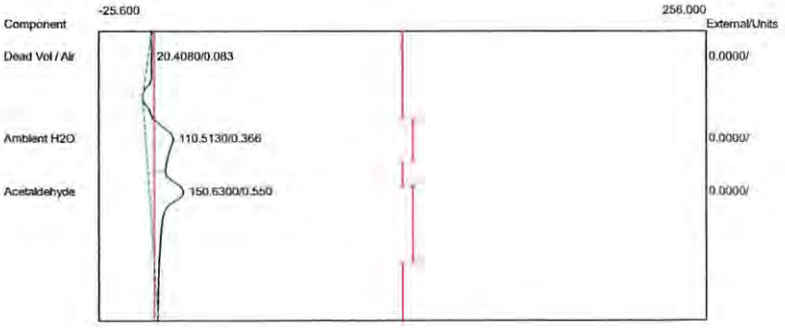
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	18.1825	0.0000	
Ambient H2O	0.366	110.9890	0.0000	
Acetaldehyde	0.550	144.5490	0.0000	
		273.7205	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 13:38:07
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A03.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



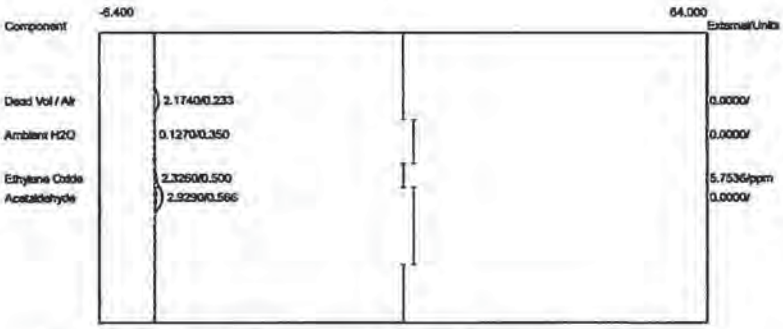
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1530	0.0000	
Ambient H2O	0.350	0.1100	0.0000	
Ethylene Oxide	0.500	2.4700	6.1098	ppm
Acetaldehyde	0.566	2.8020	0.0000	
		7.5350	6.1098	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 13:38:07
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A03.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



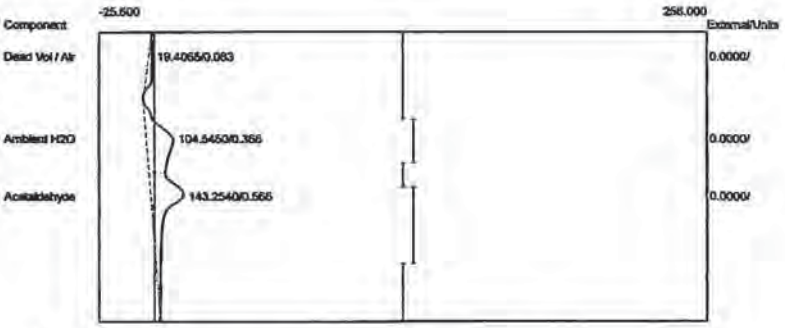
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	20.4080	0.0000	
Ambient H2O	0.366	110.5130	0.0000	
Acetaldehyde	0.550	150.6300	0.0000	
		281.5510	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 13:33:15
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A02.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



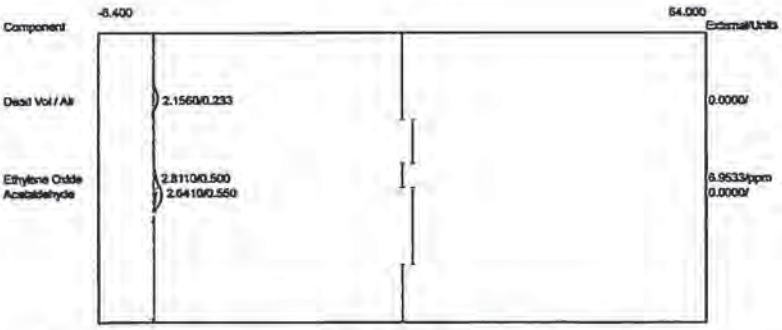
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1740	0.0000	
Ambient H2O	0.350	0.1270	0.0000	
Ethylene Oxide	0.500	2.3260	5.7536	ppm
Acetaldehyde	0.566	2.9290	0.0000	
		7.5560	5.7536	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 13:33:15
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A02.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



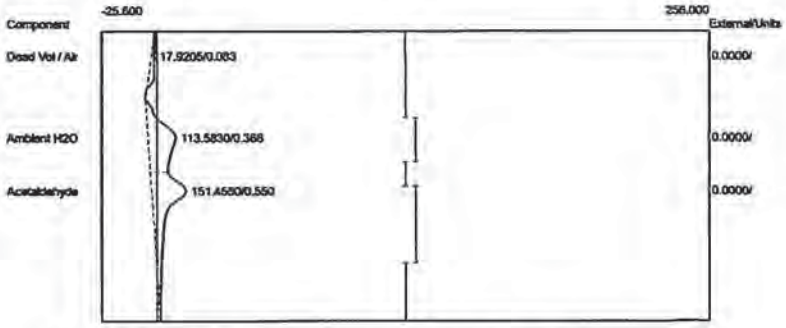
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	19.4065	0.0000	
Ambient H2O	0.366	104.5450	0.0000	
Acetaldehyde	0.566	143.2540	0.0000	
		267.2055	0.0000	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/27/2018 13:28:08
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2018-3A01.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.1560	0.0000	
Ethylene Oxide	0.500	2.8110	6.9533	ppm
Acetaldehyde	0.550	2.6410	0.0000	
		7.6080	6.9533	

Lab name: ECSi
Client: Cook Medical
Client ID: Run#3Aer
Analysis date: 07/28/2018 13:28:08
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2018-3A01.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.083	17.9205	0.0000	
Ambient H2O	0.366	113.5830	0.0000	
Acetaldehyde	0.550	151.4580	0.0000	
		282.9615	0.0000	

APPENDIX H

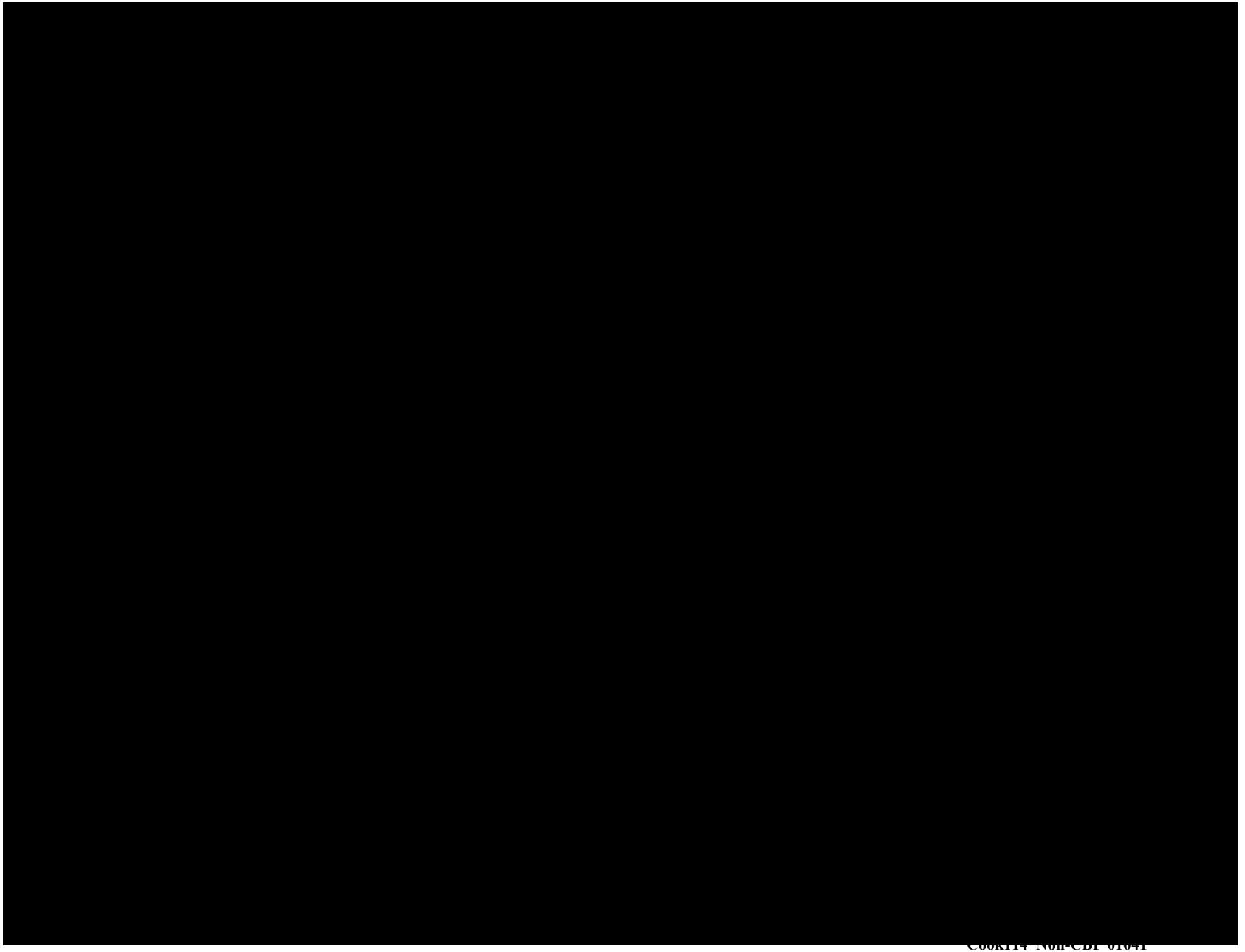
Cycle Data Reports

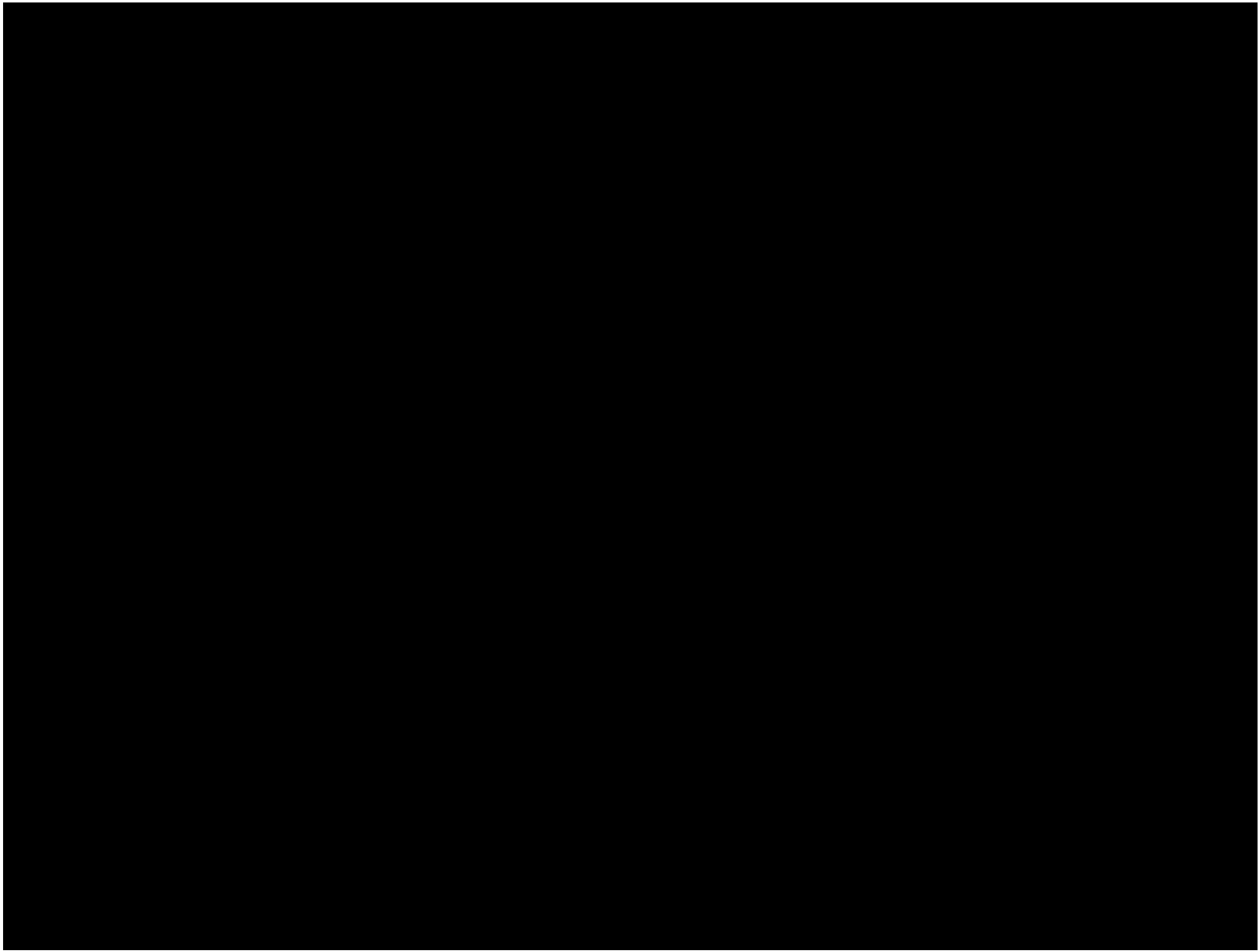
[redacted]

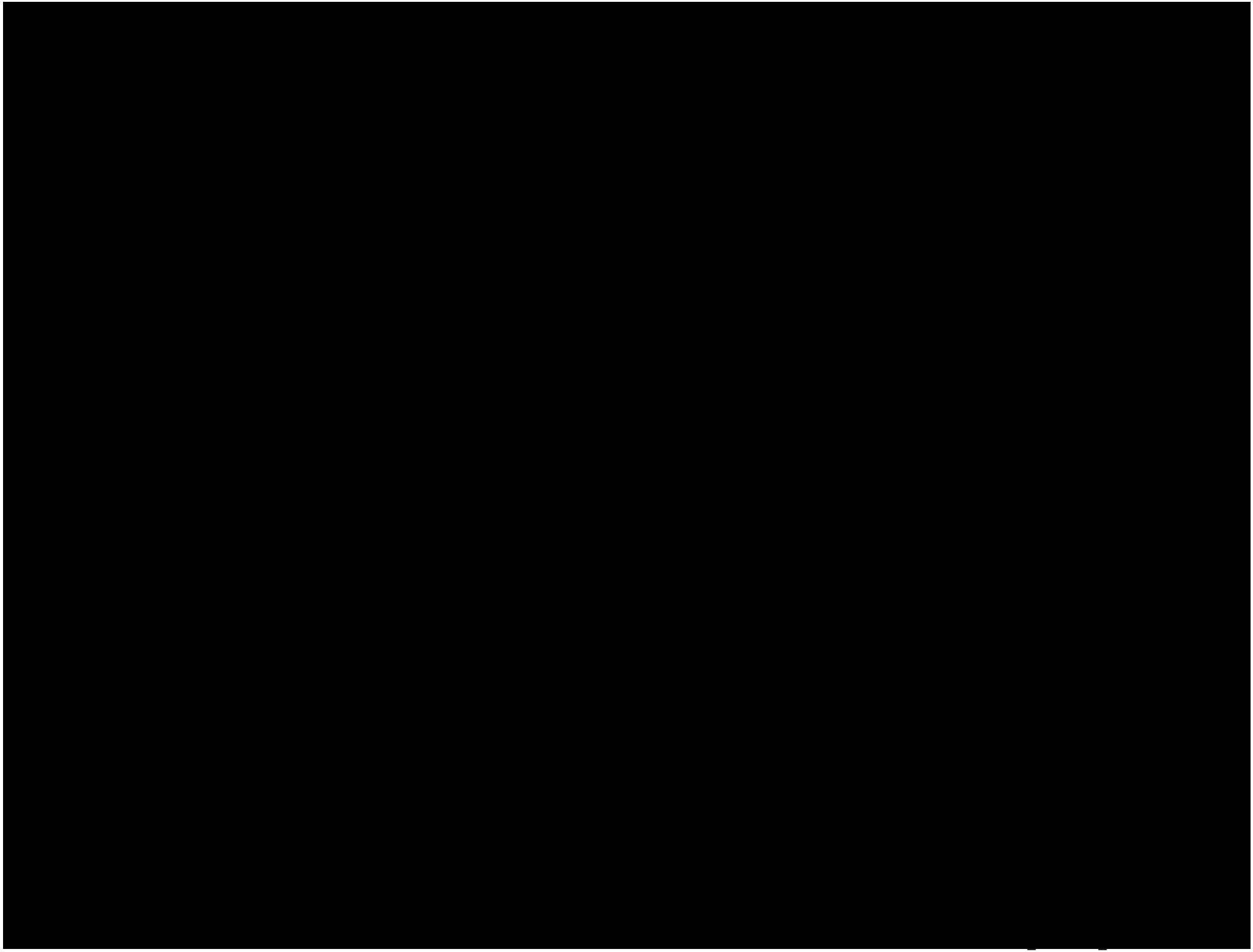
SCV Test #1

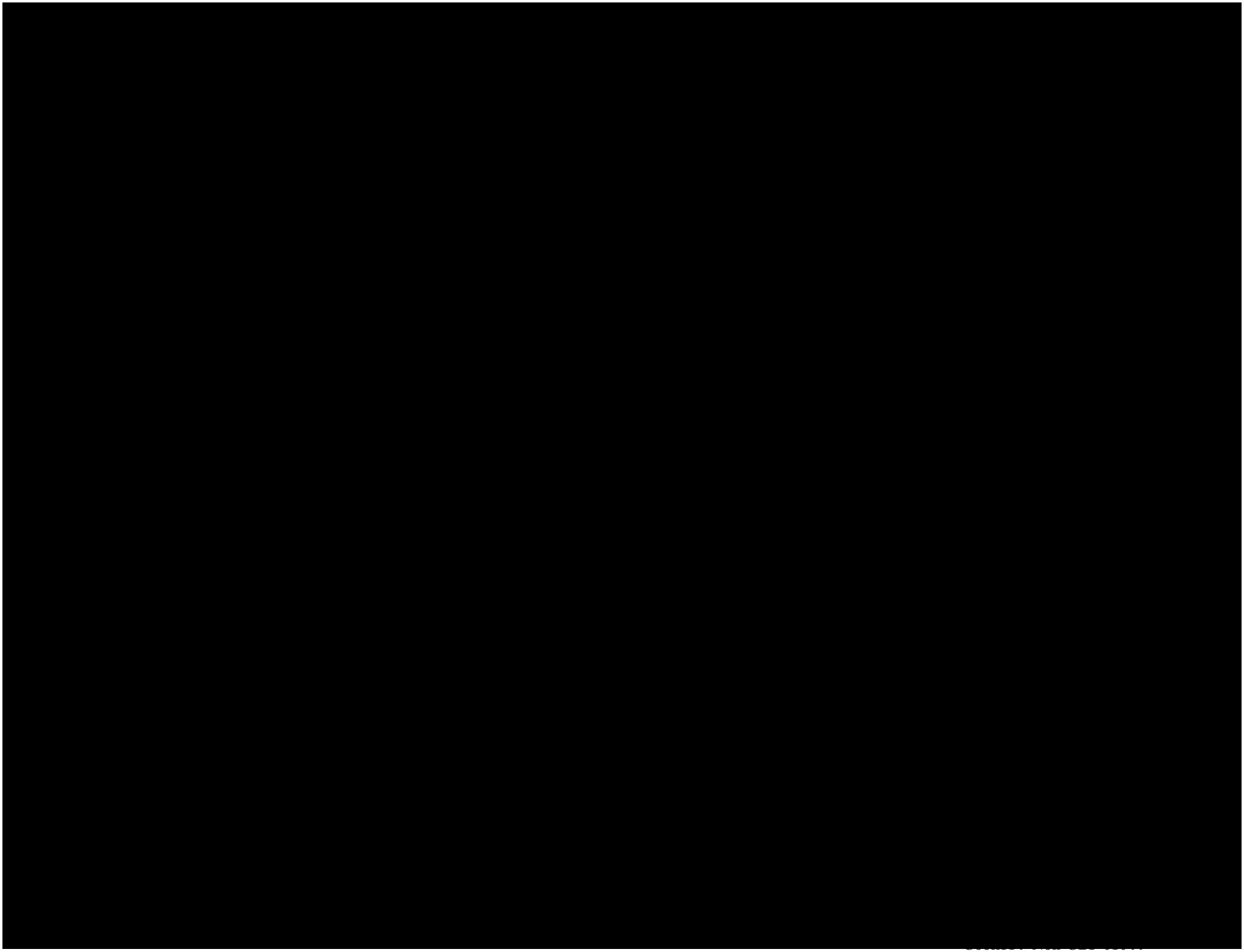
Sterilizers S1, S4, S8 & S9

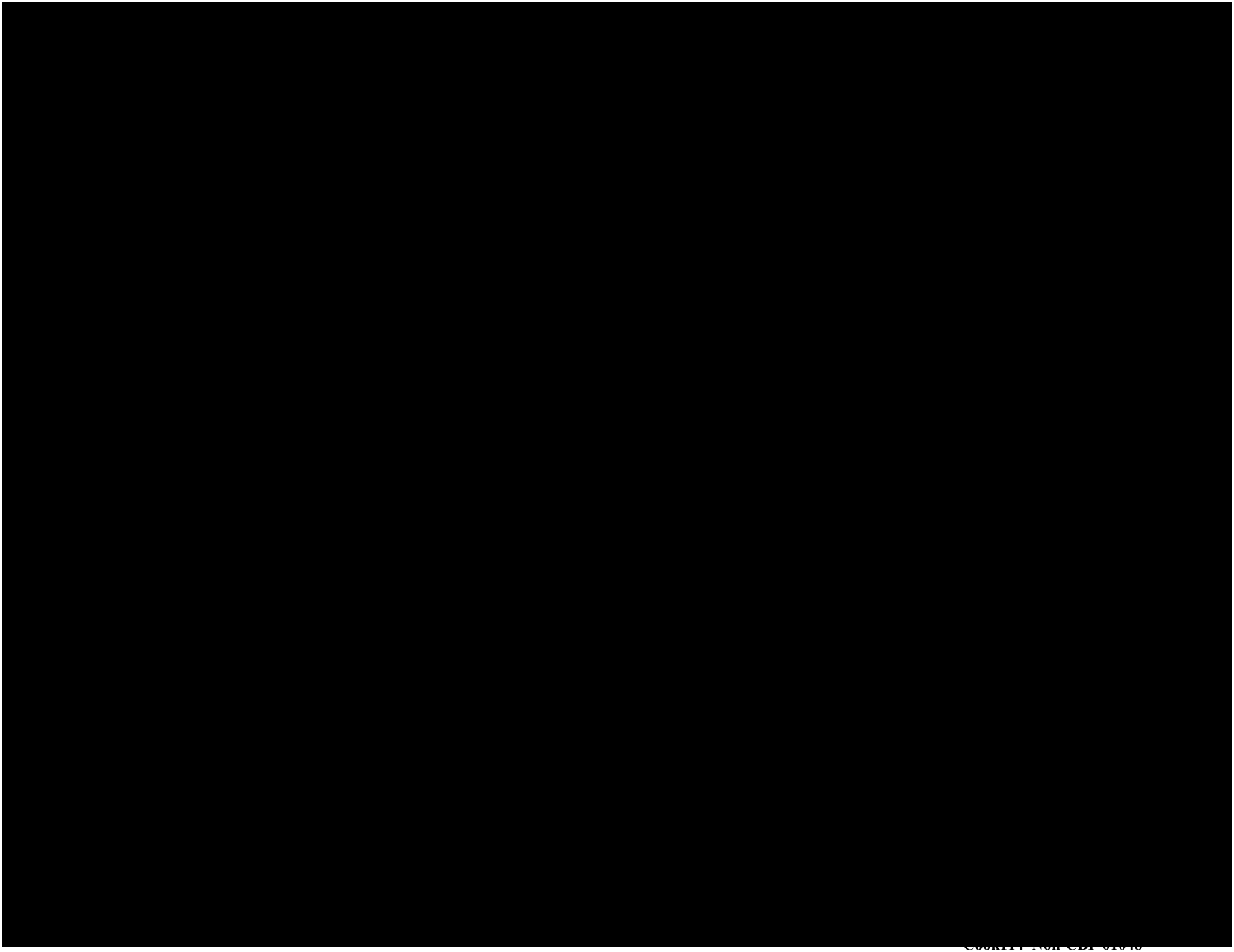
[redacted]

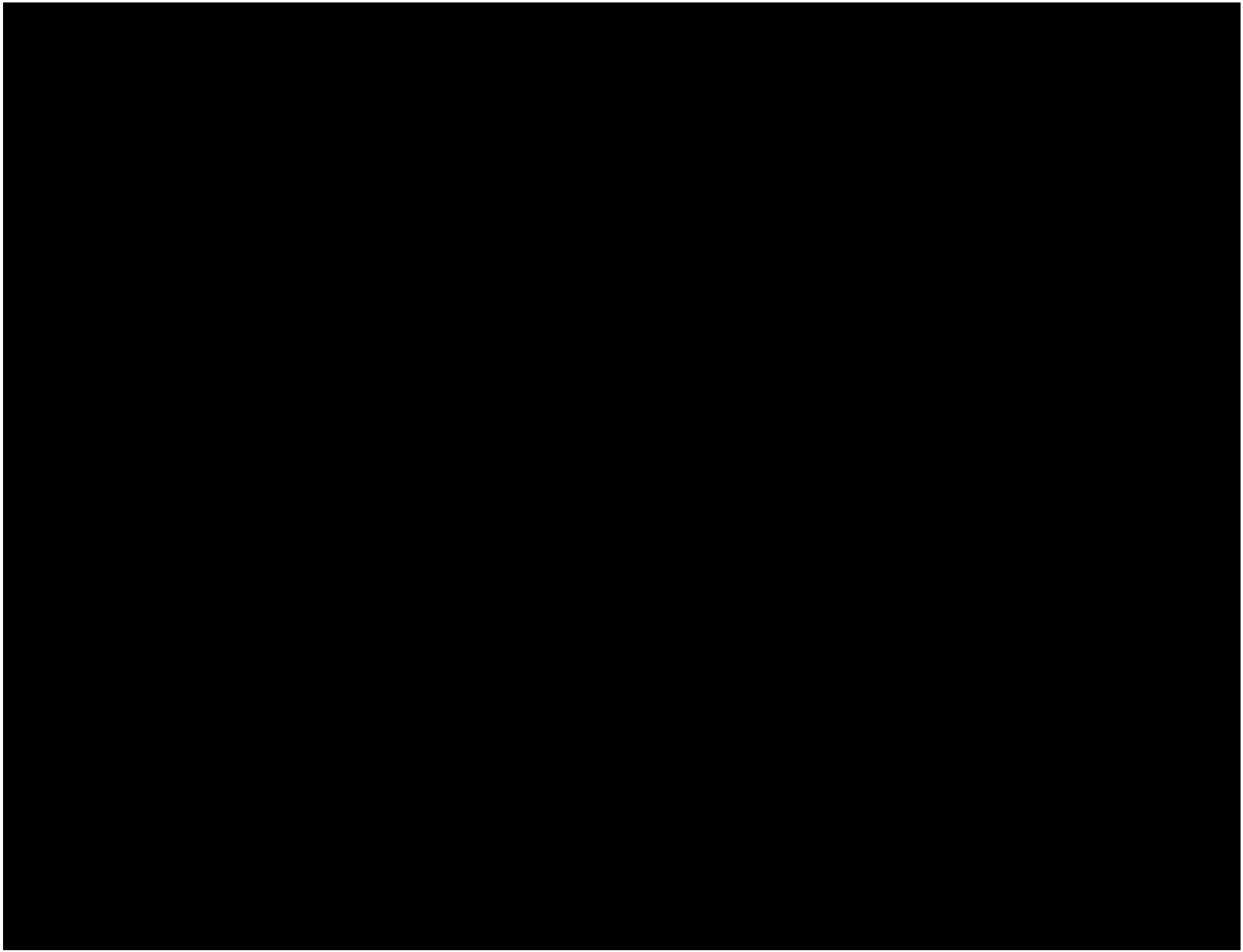


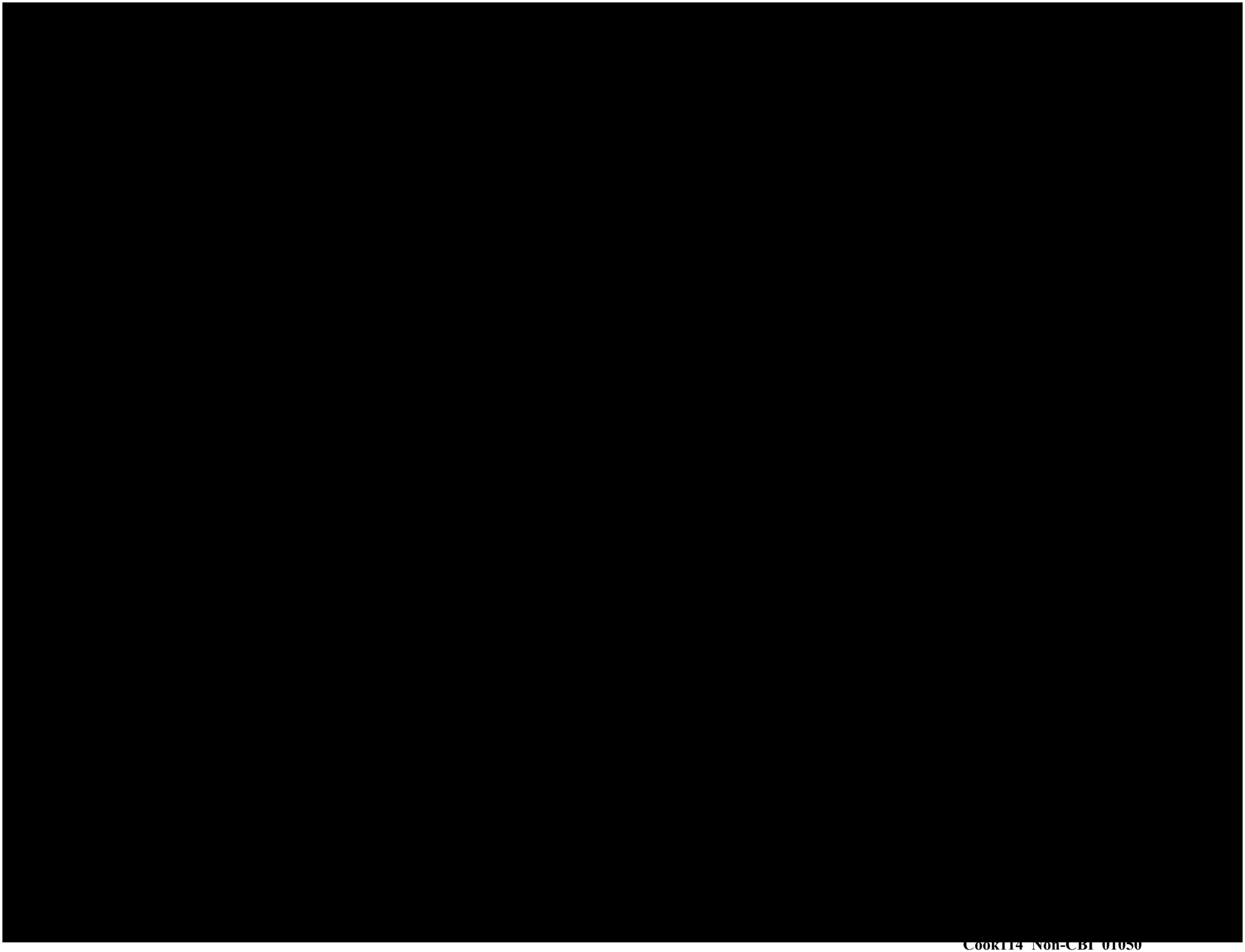


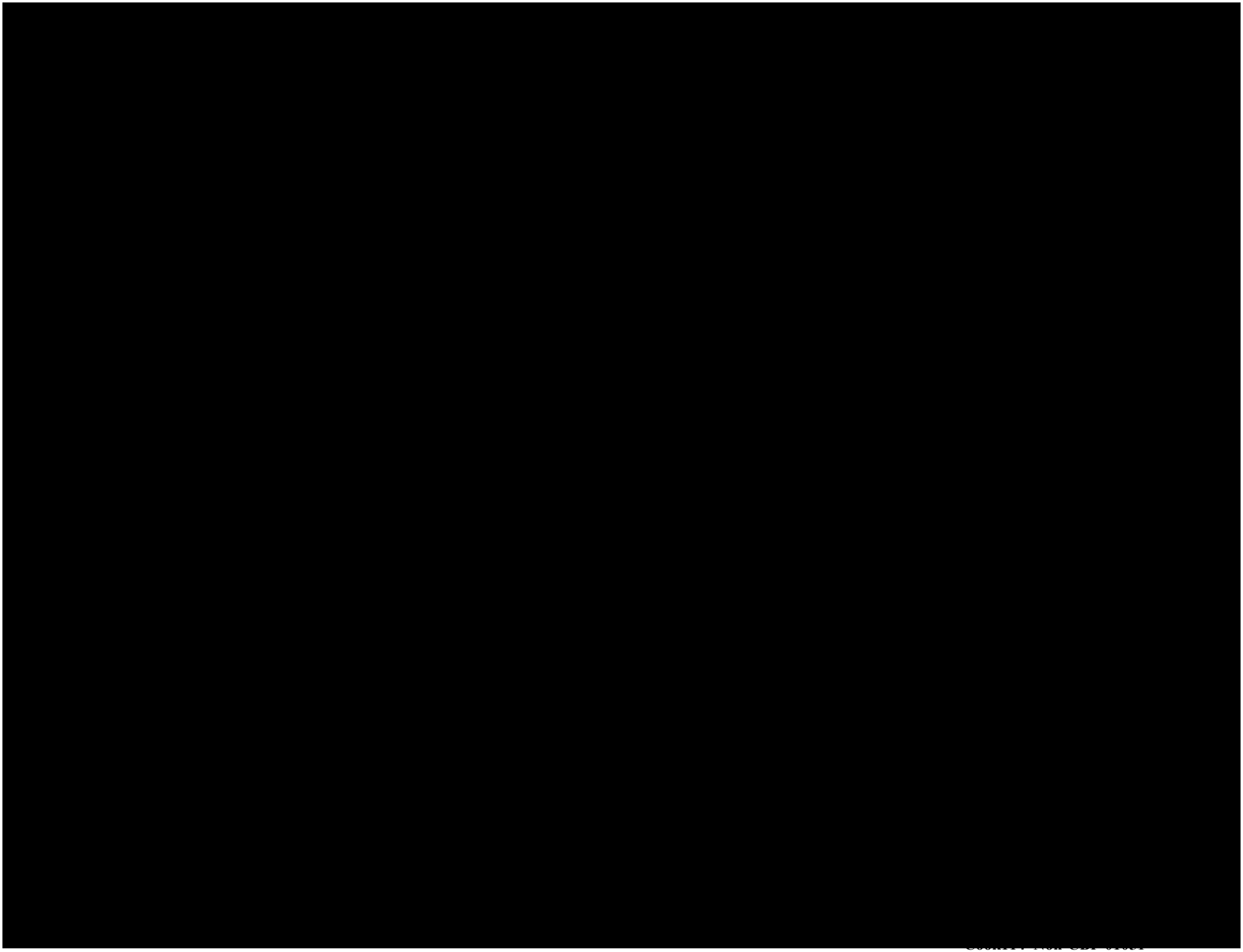


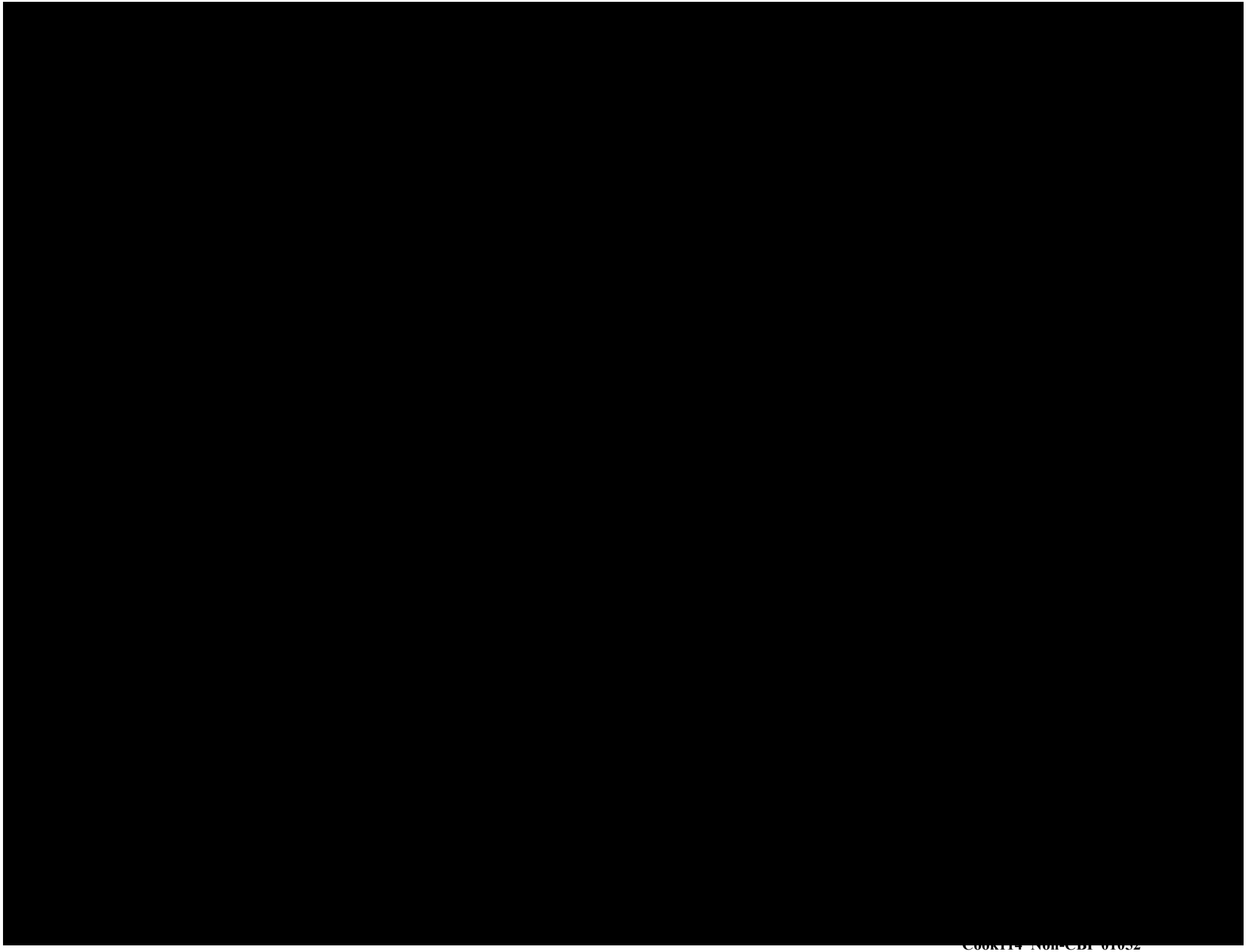


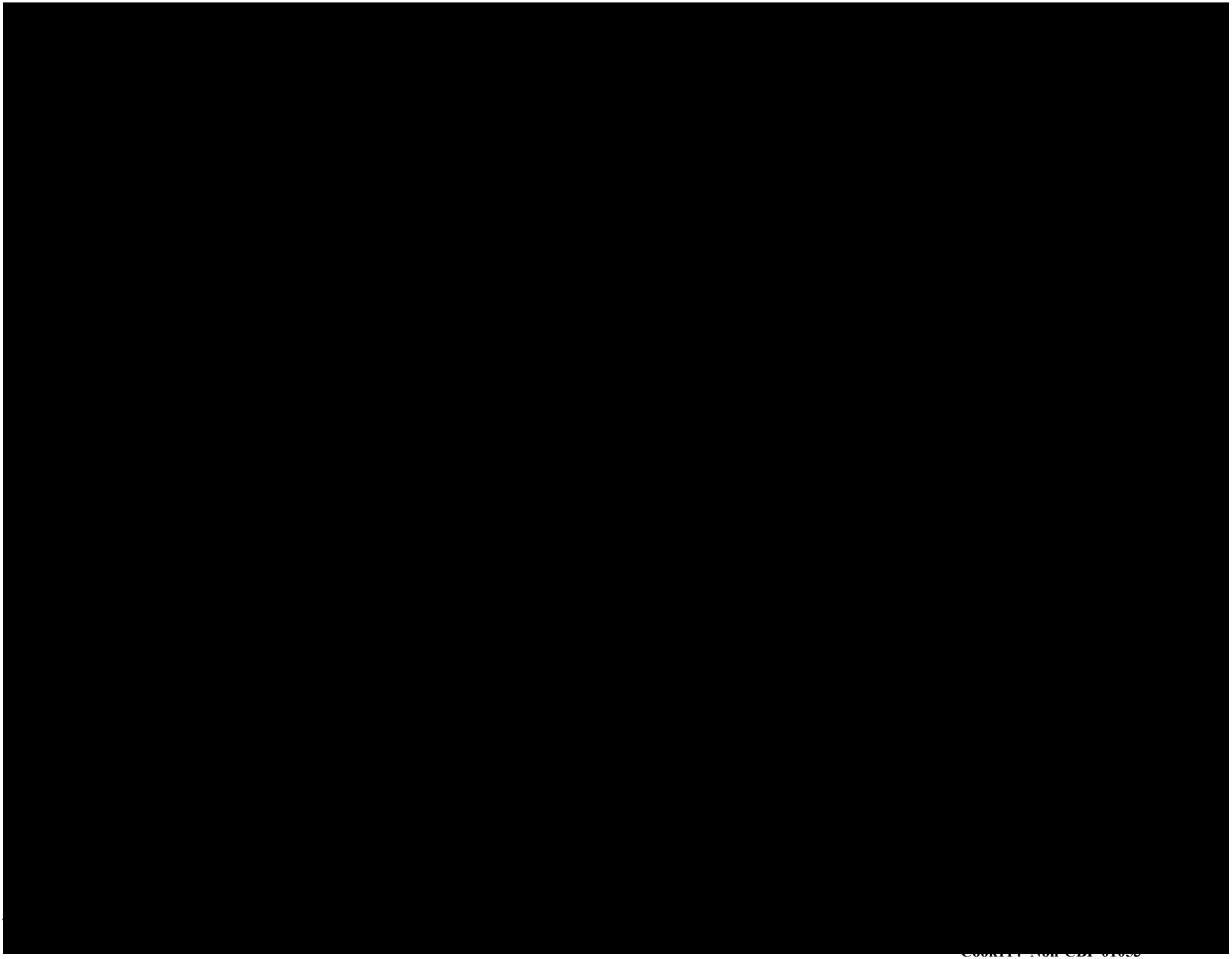


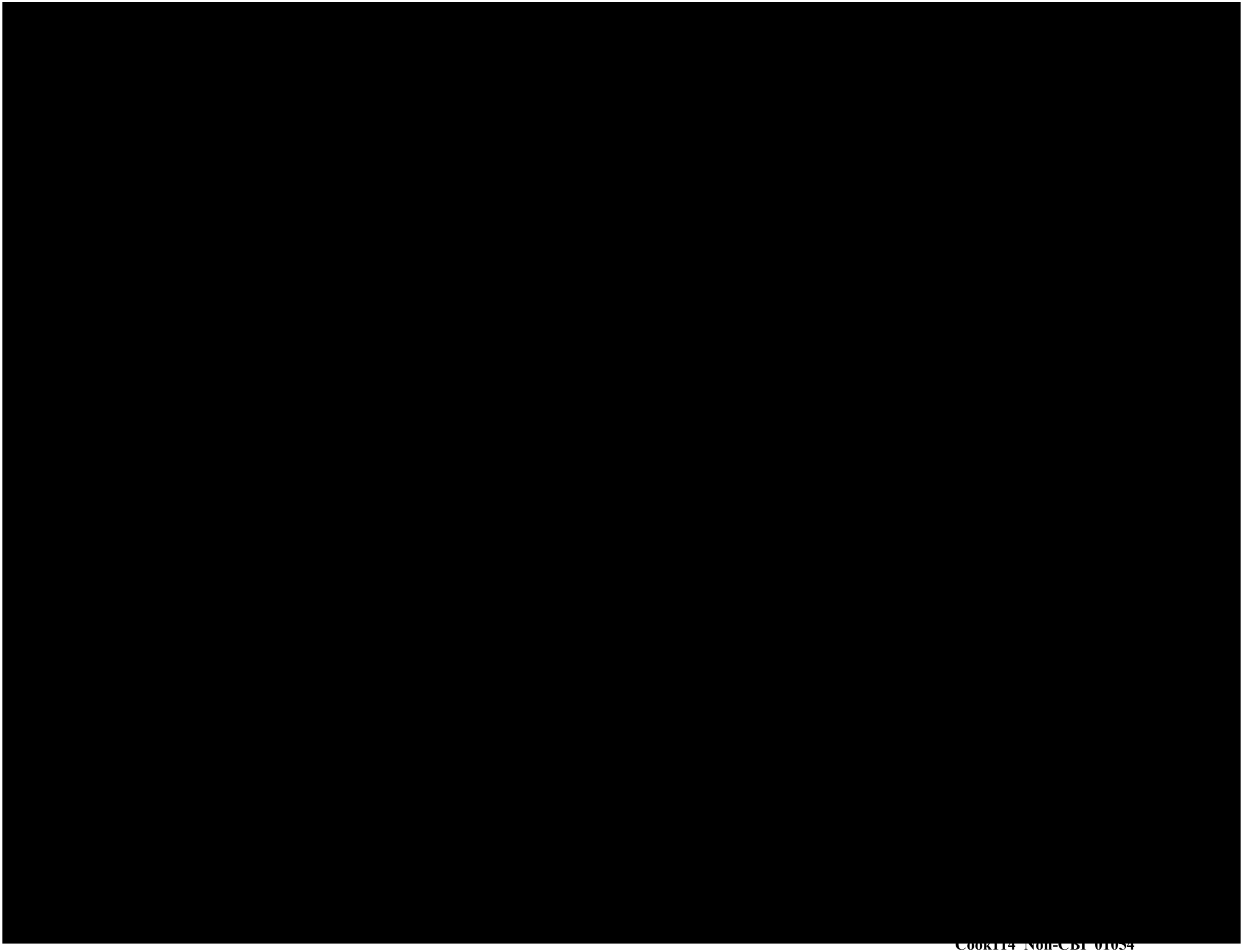


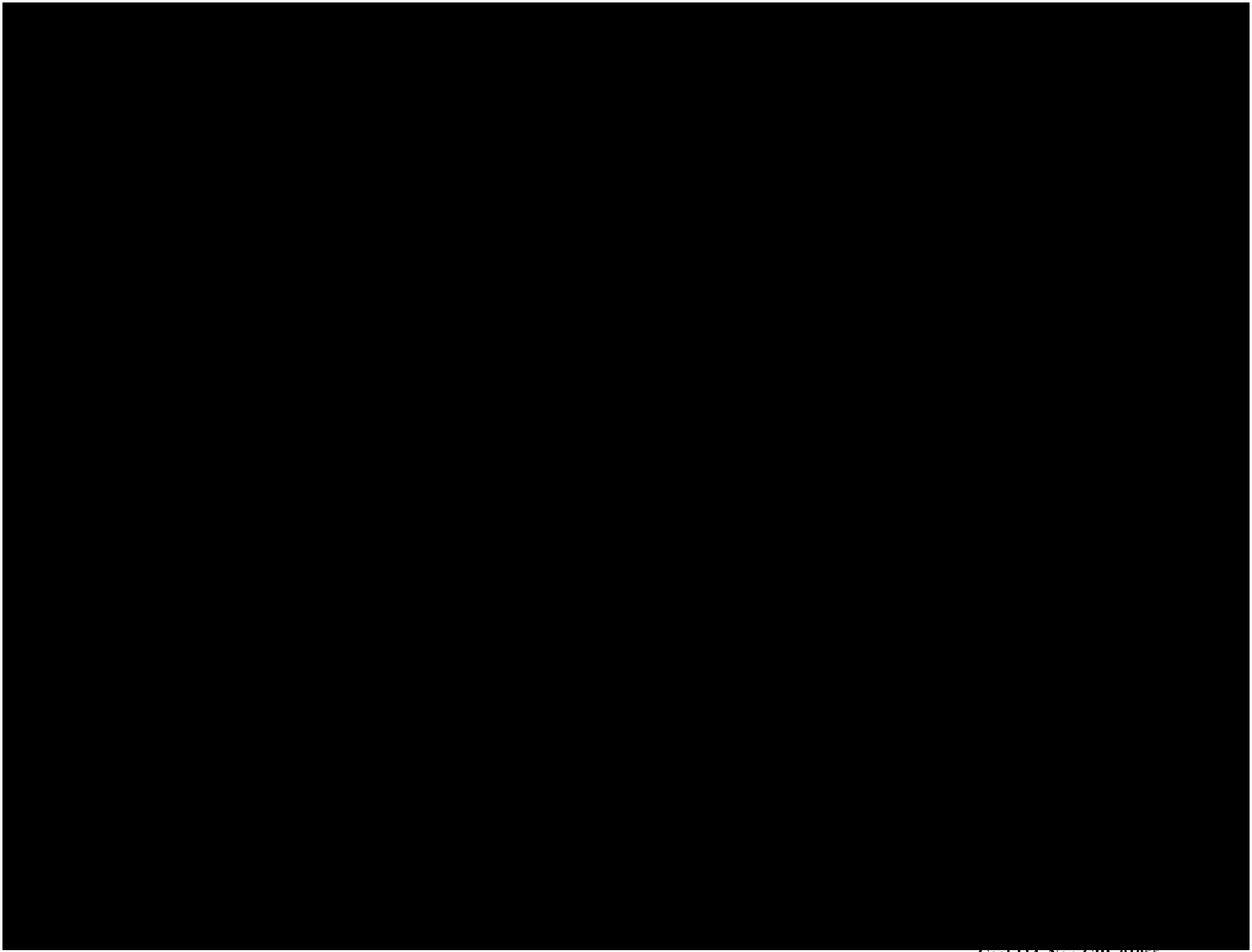


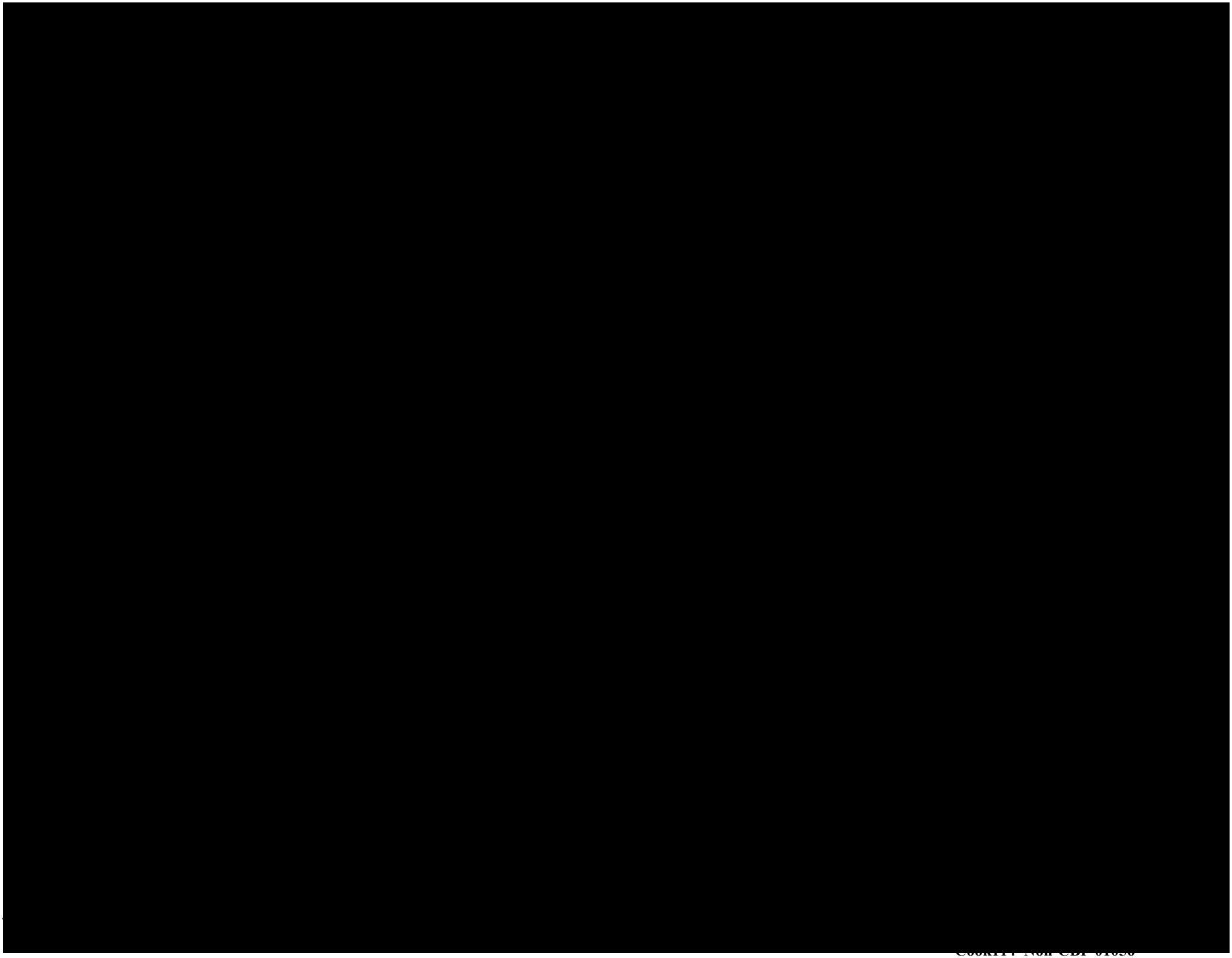


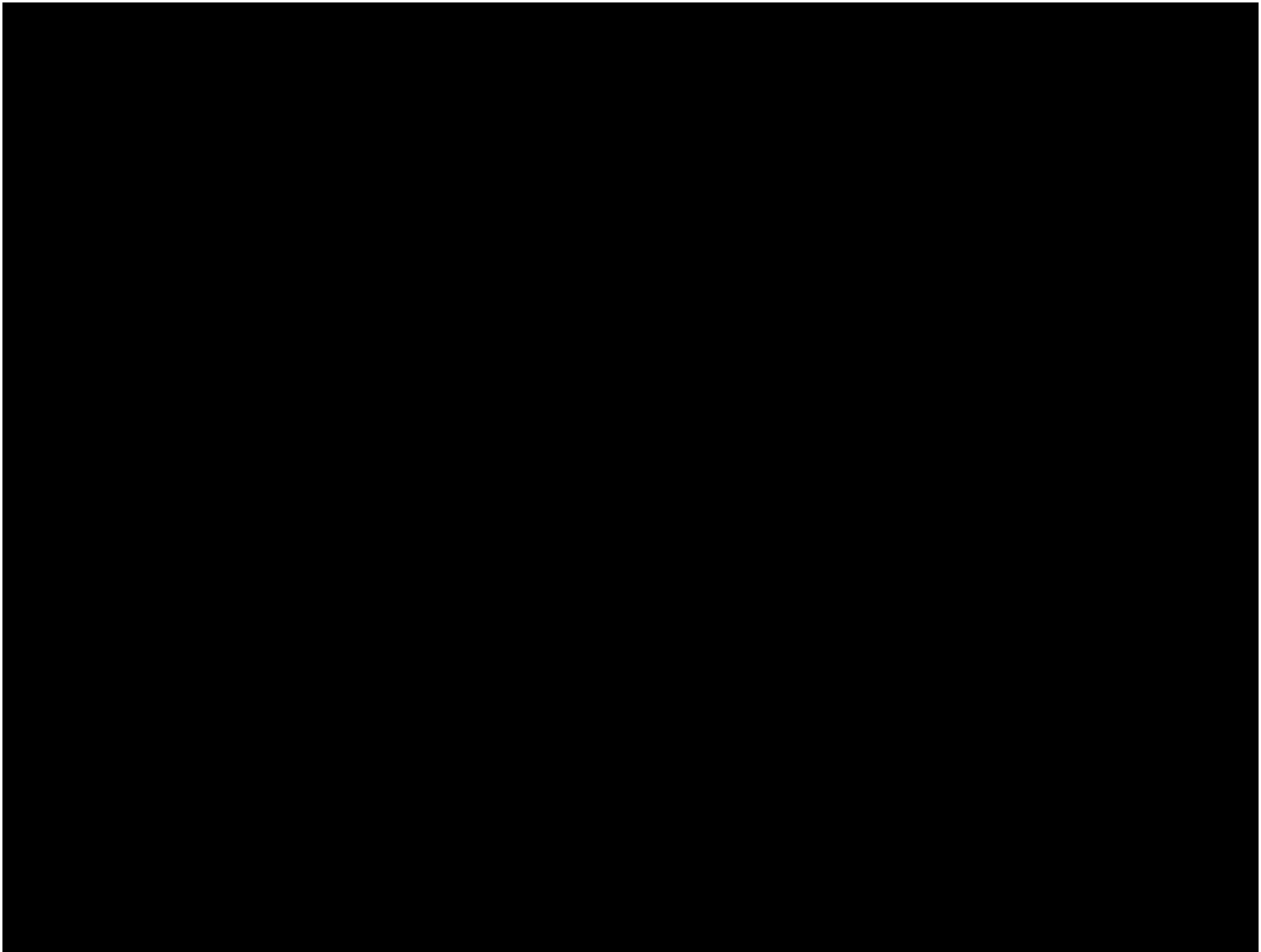


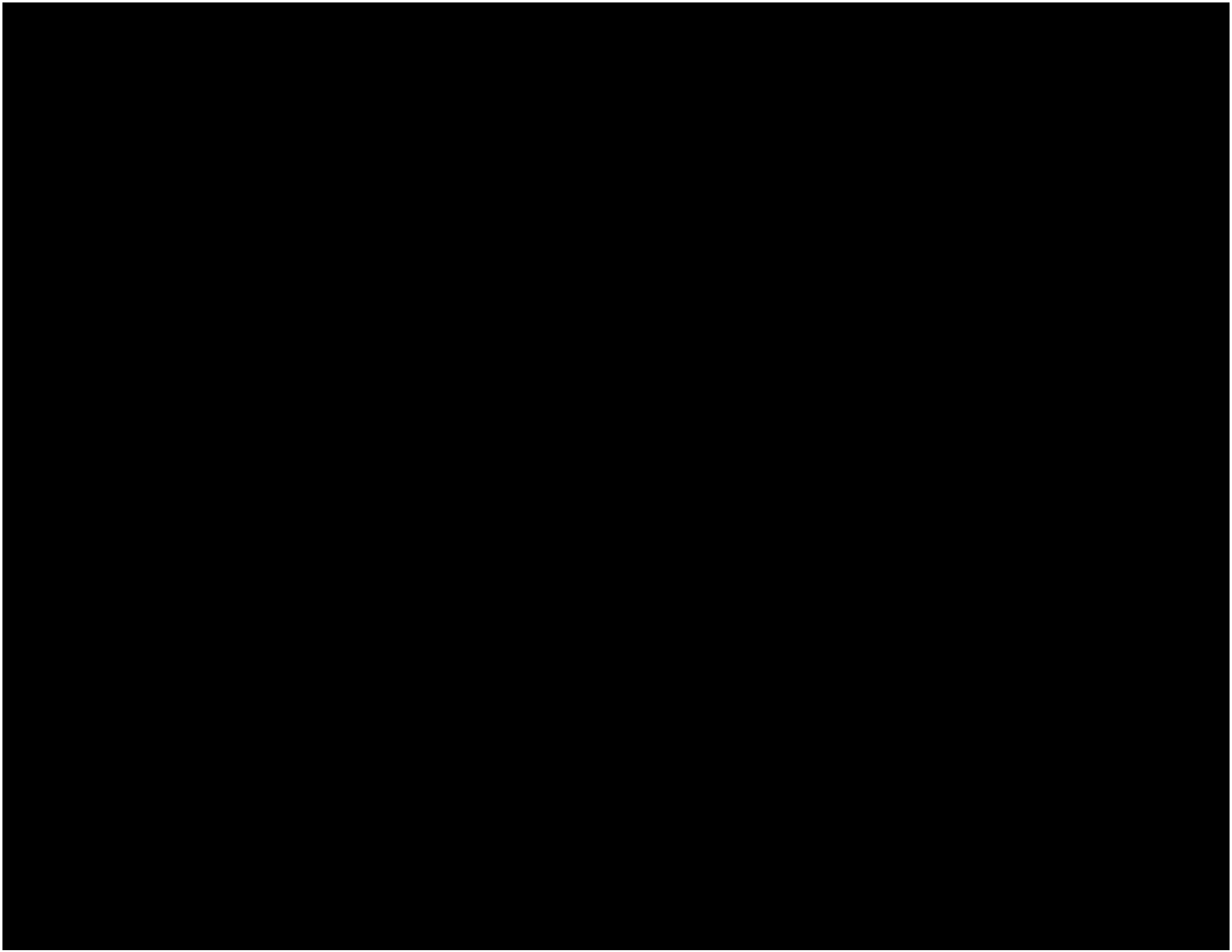


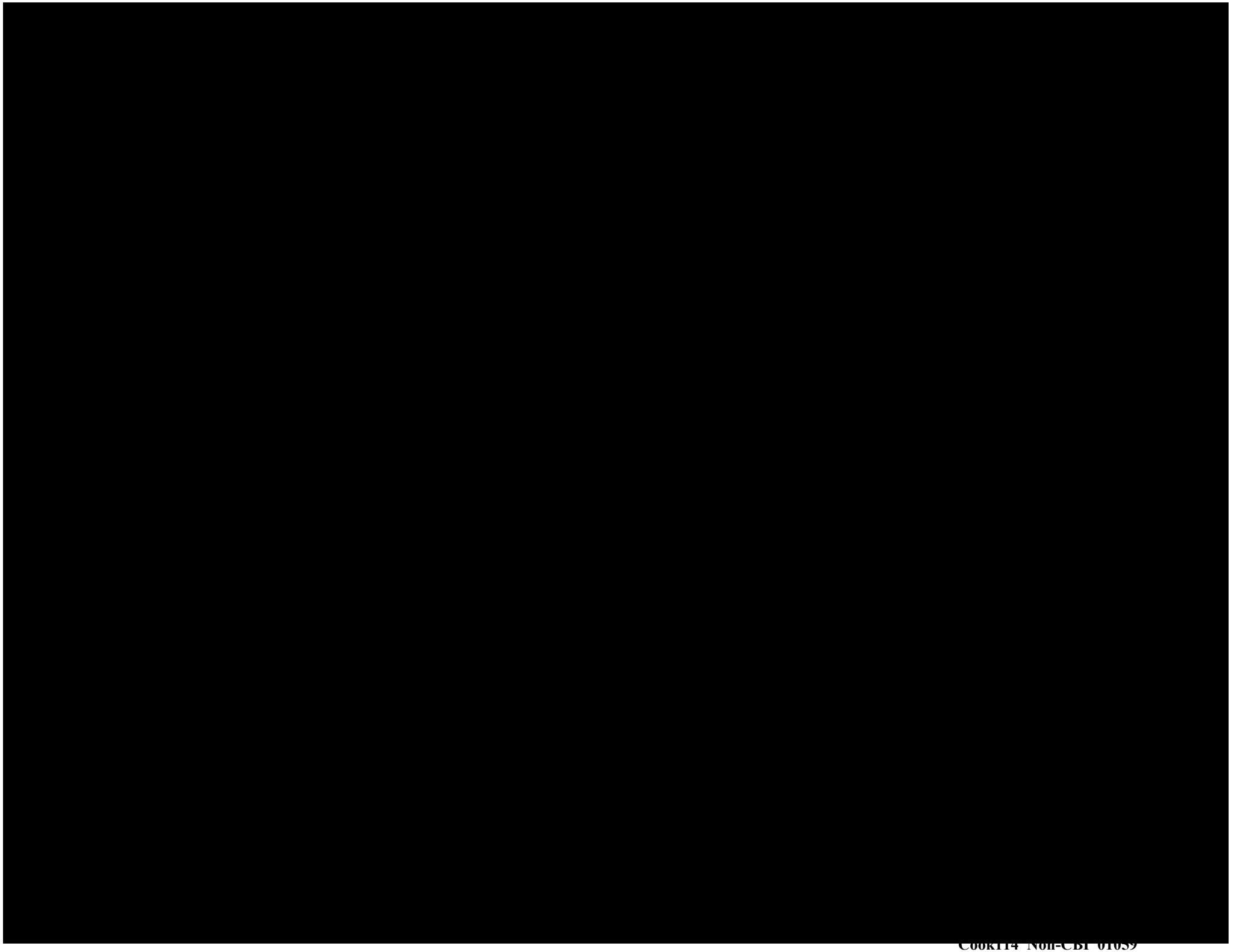


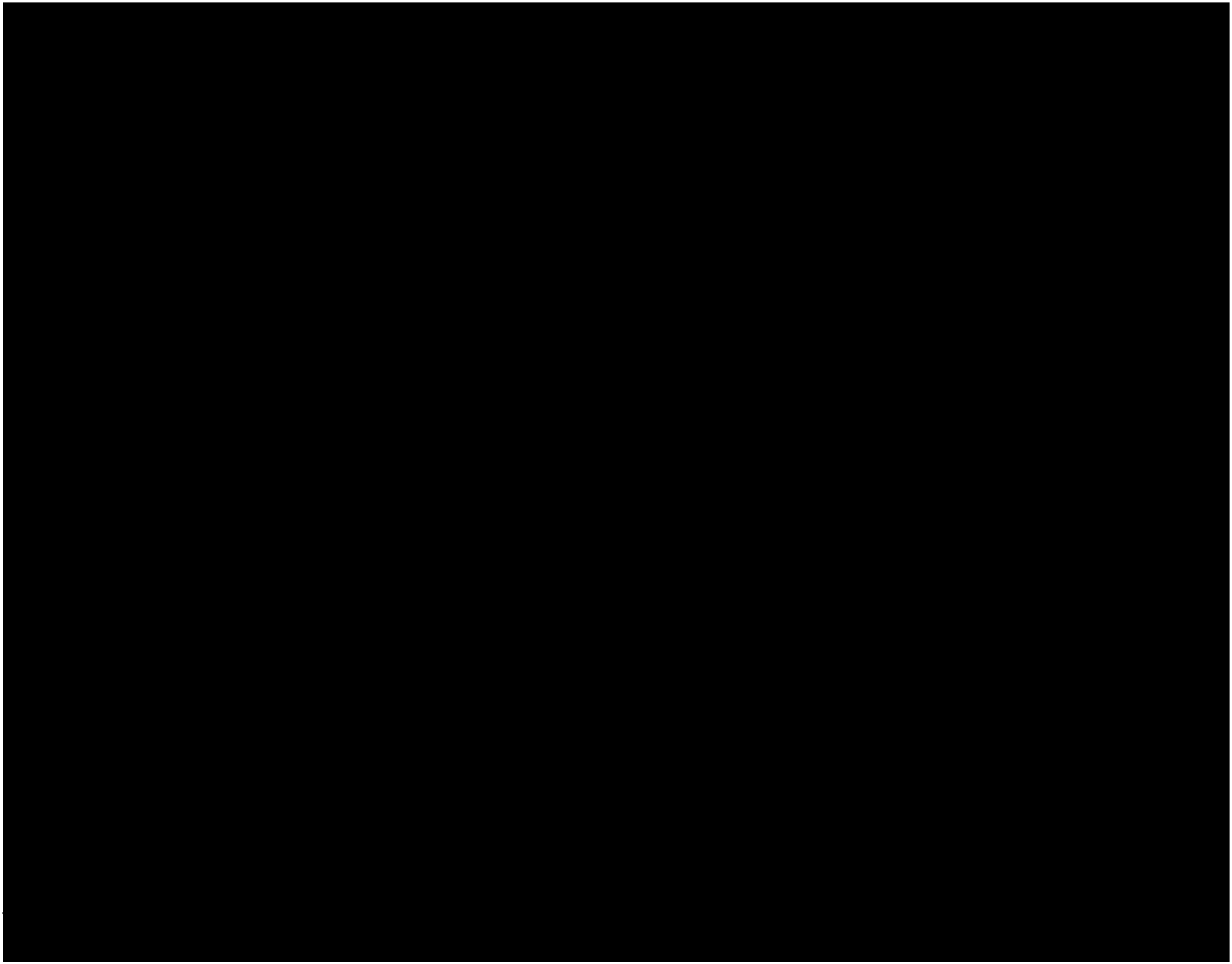


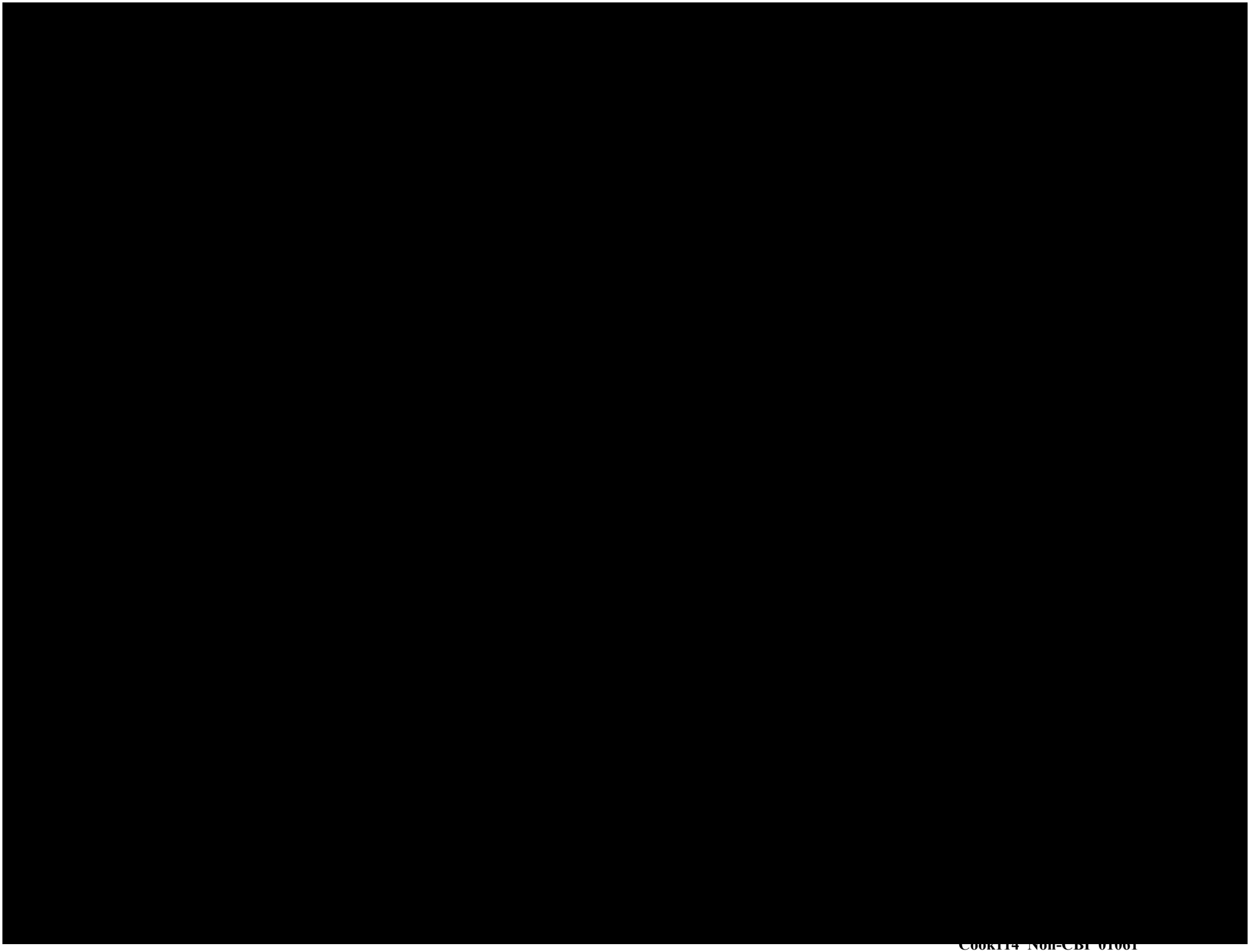


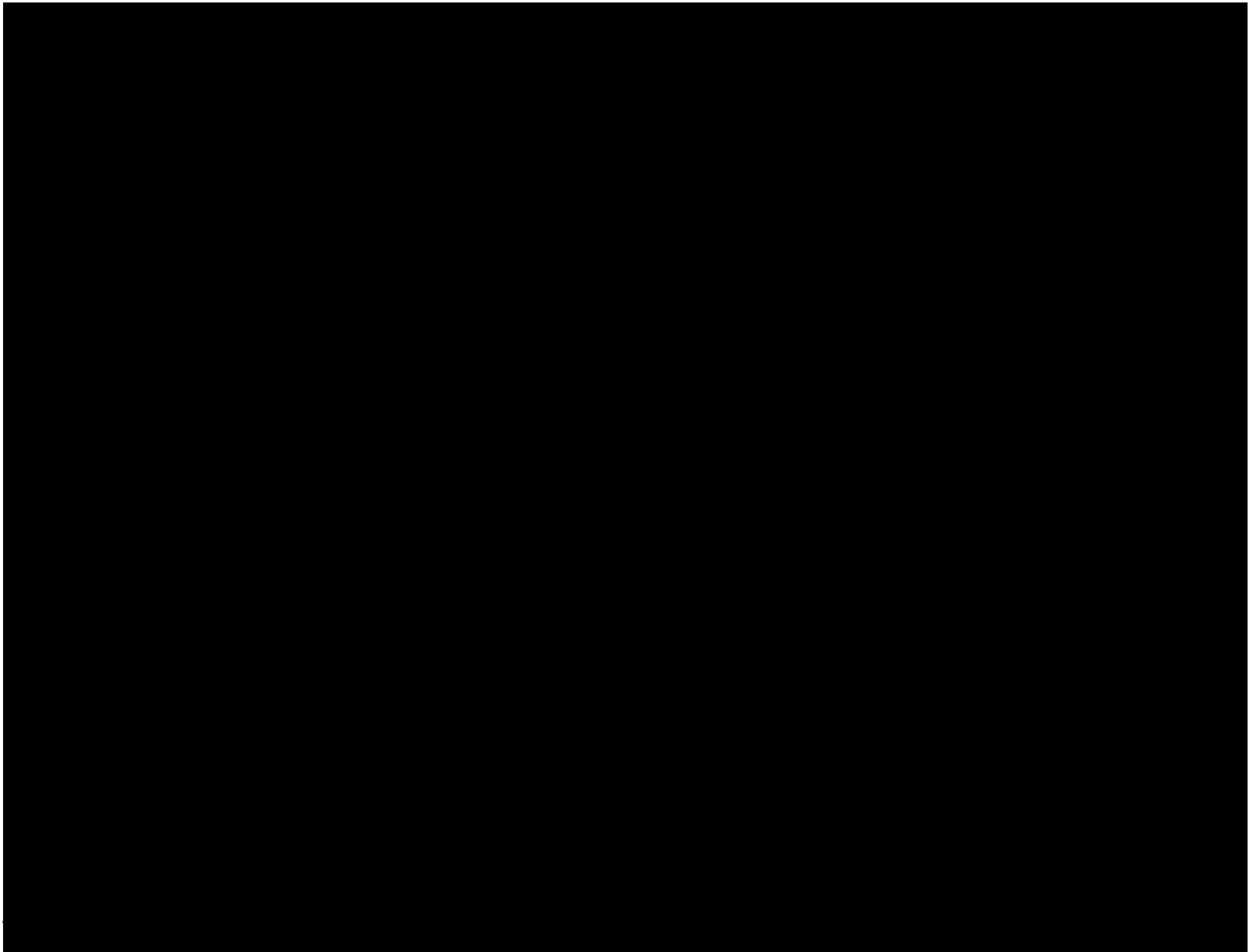


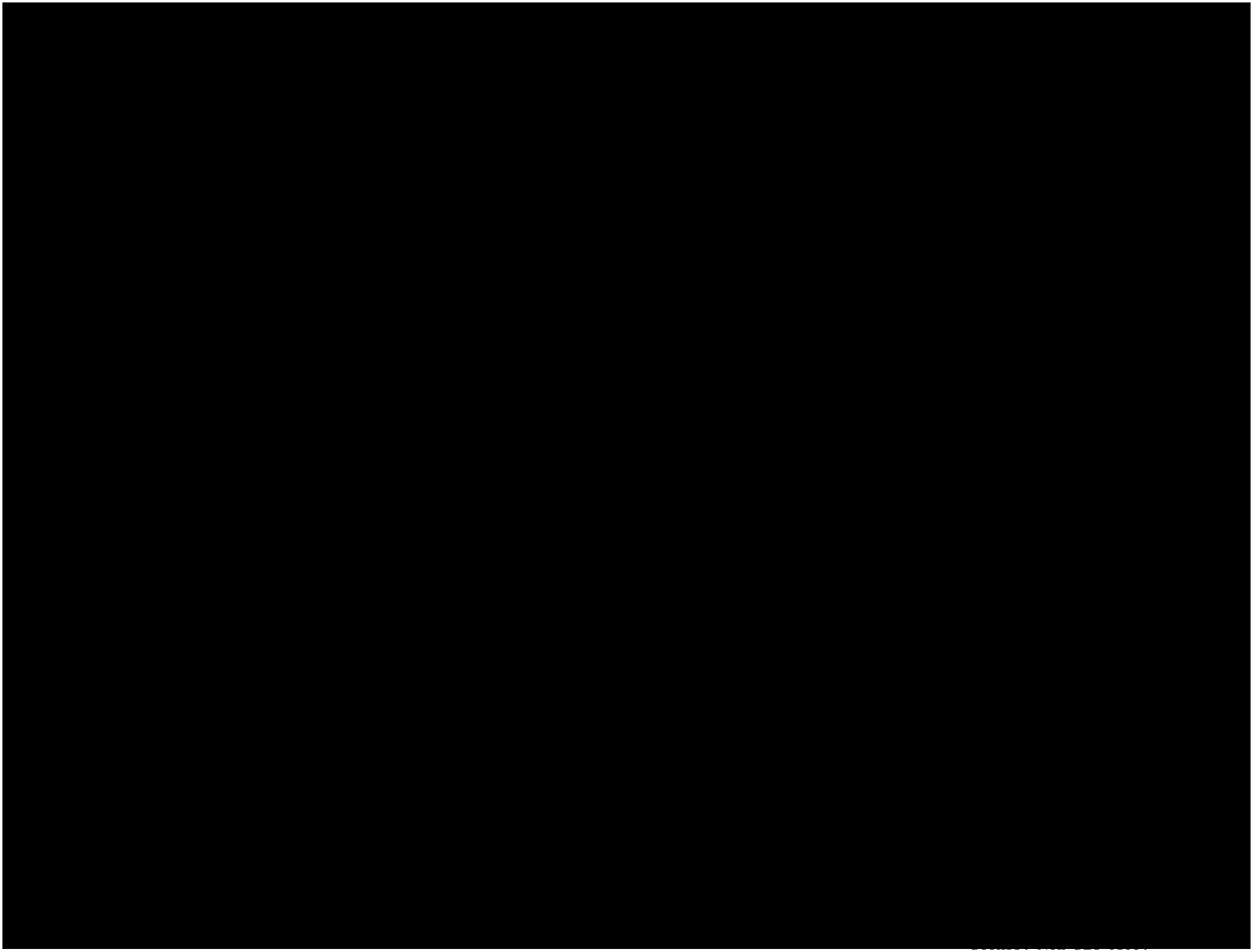


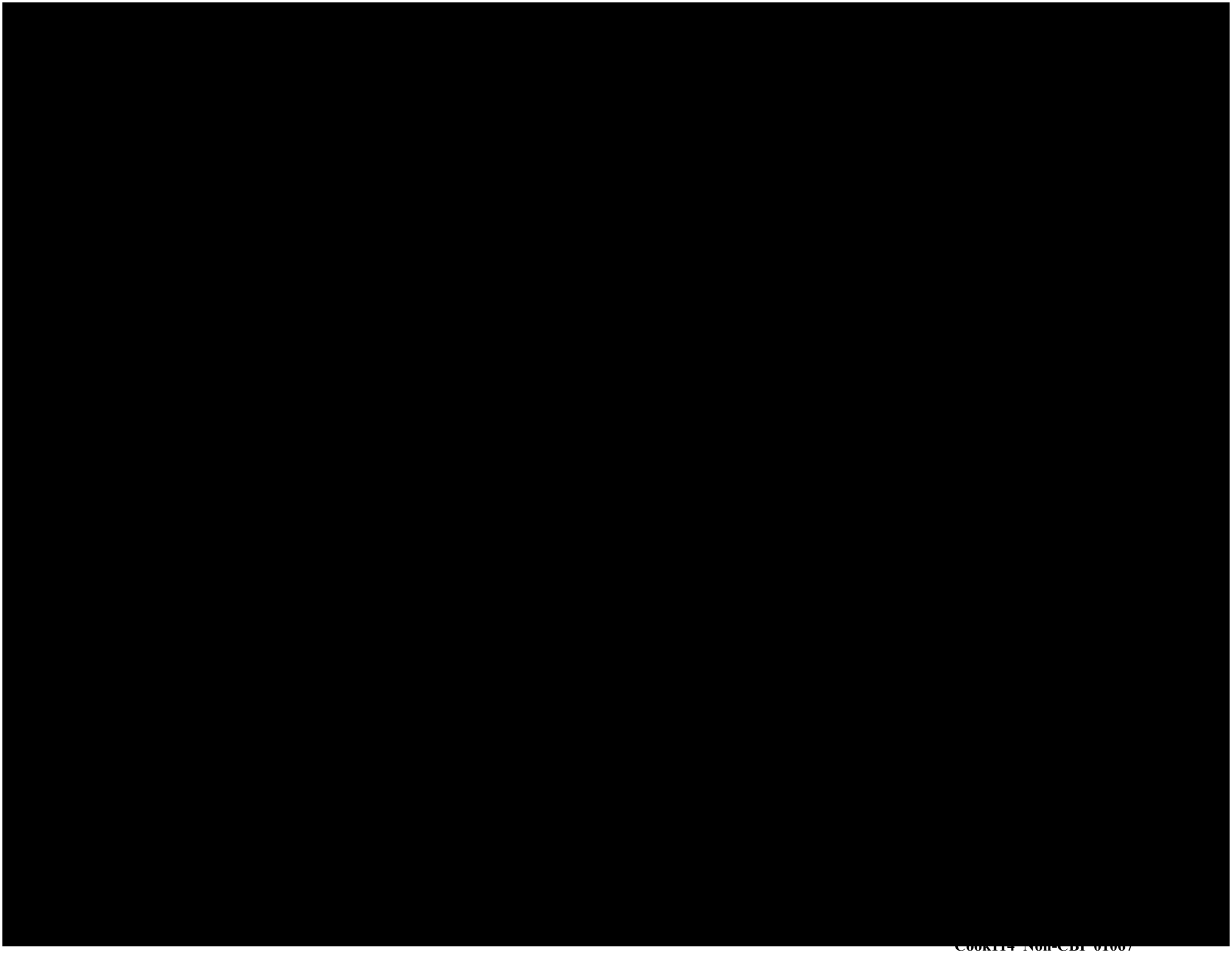


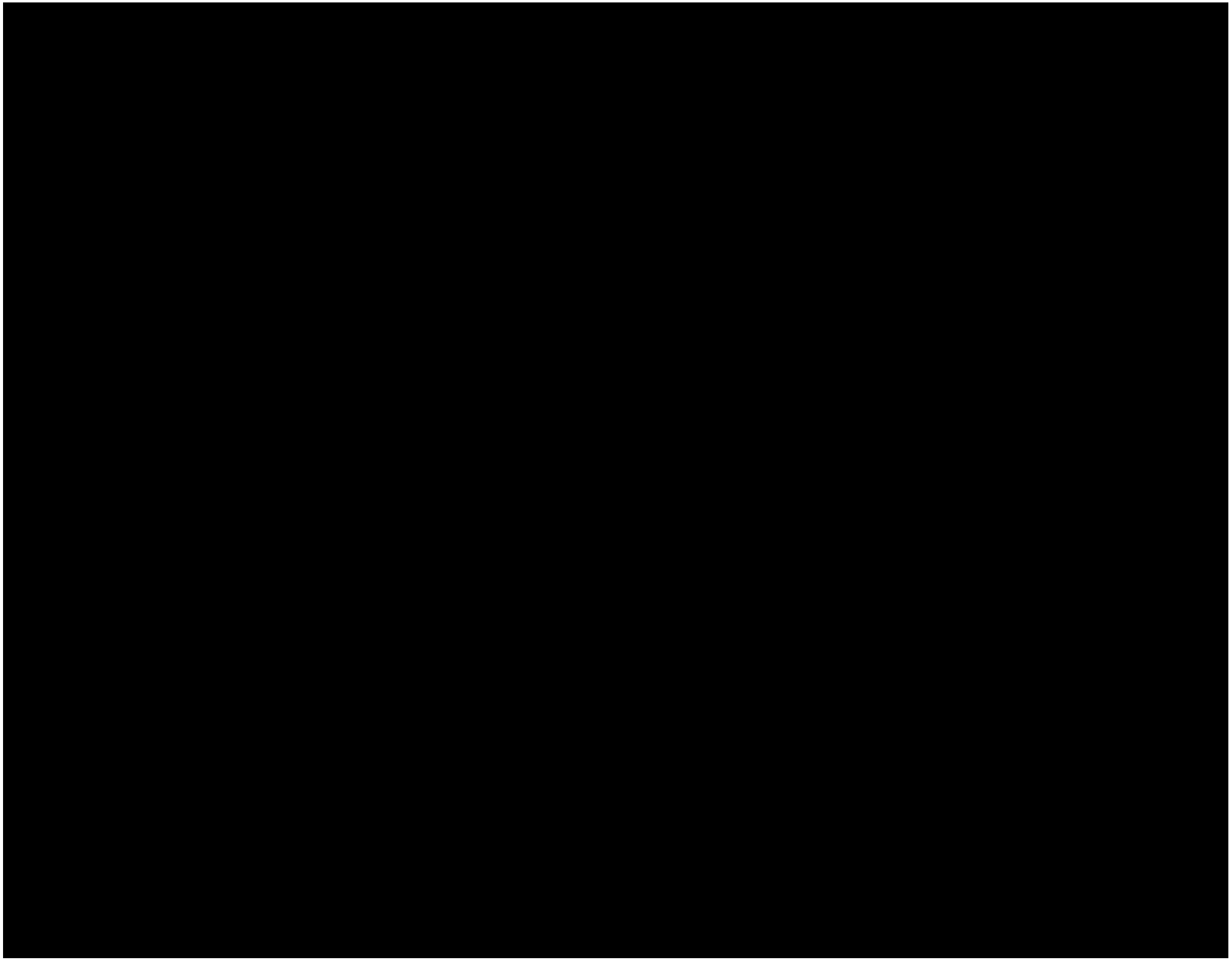


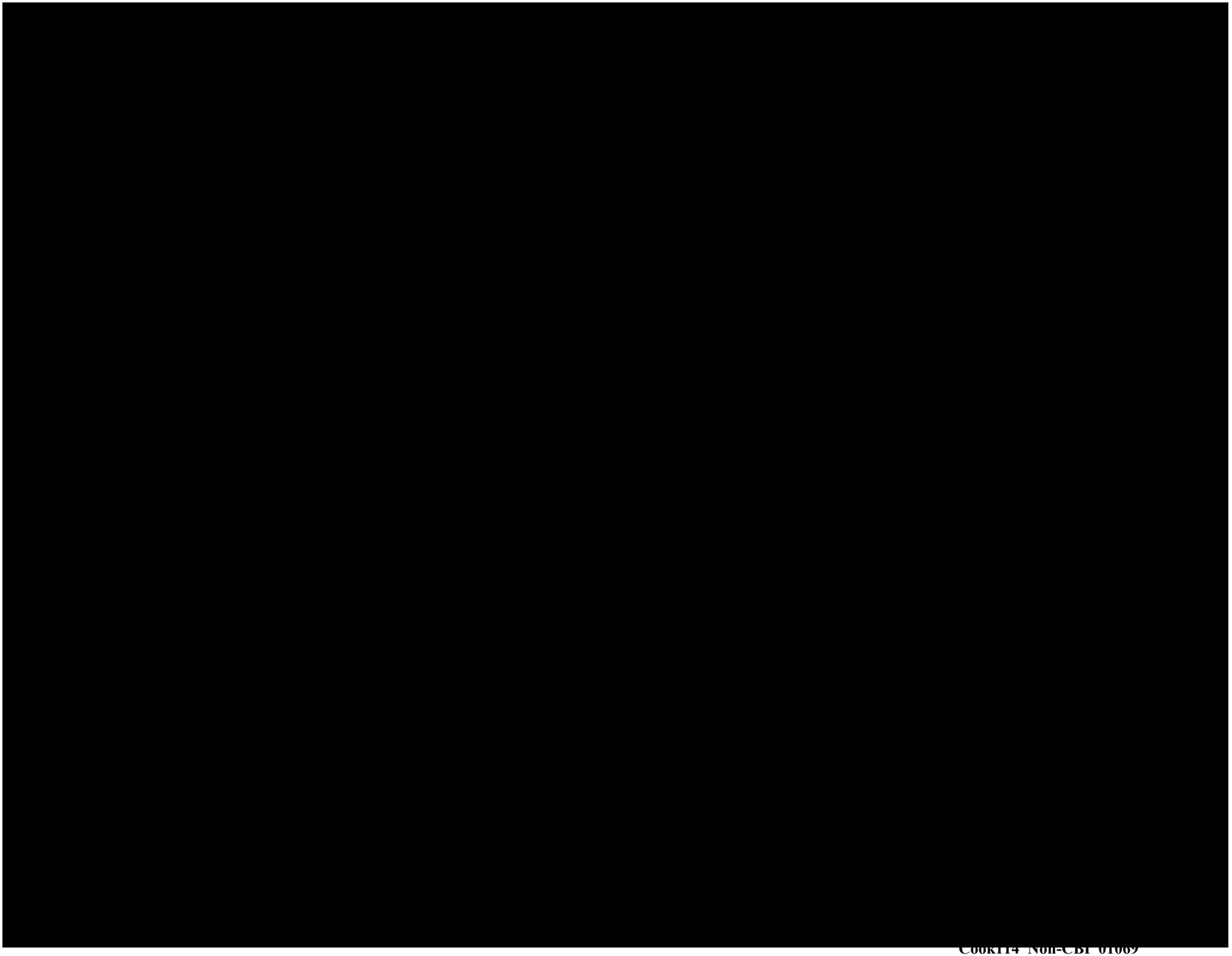


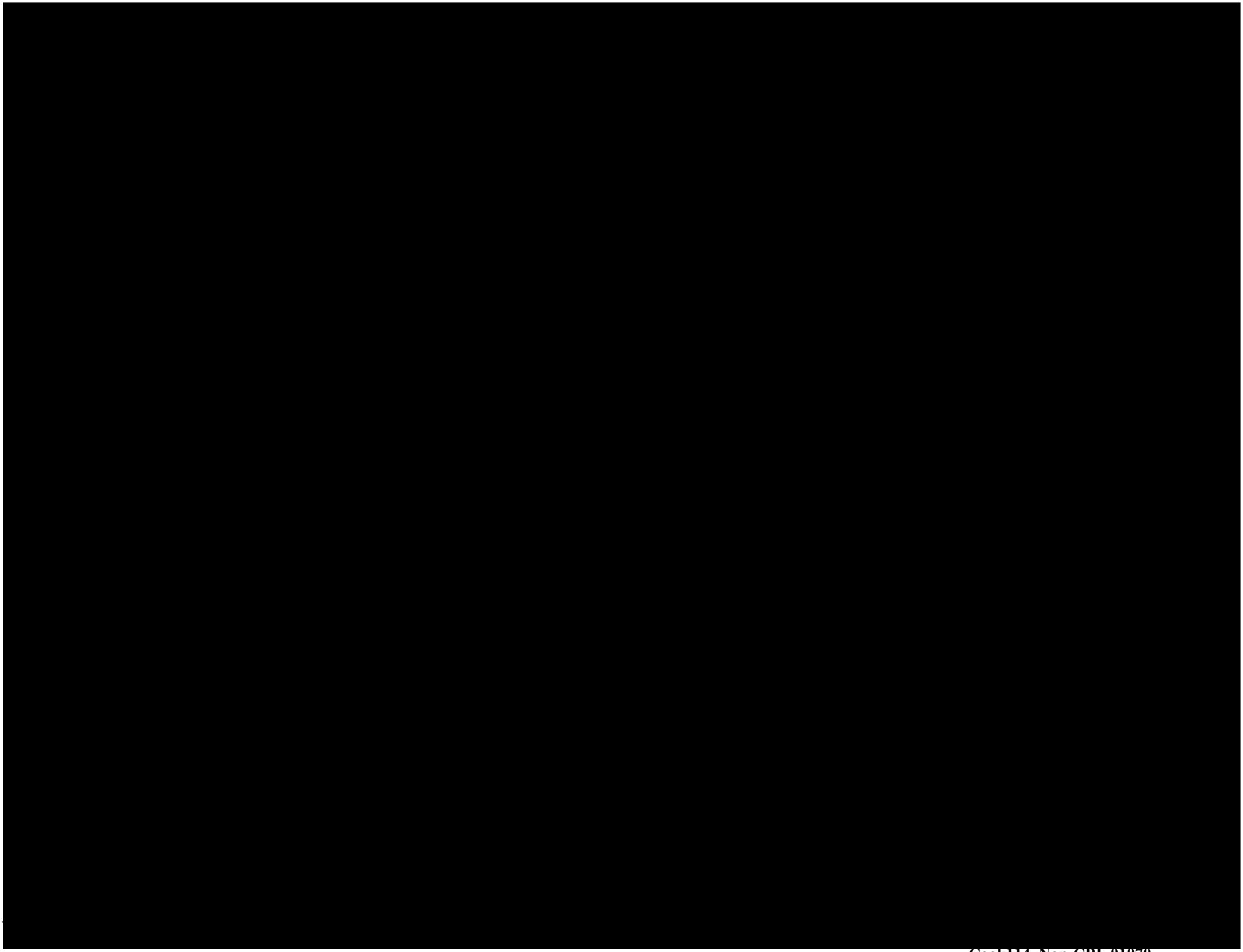


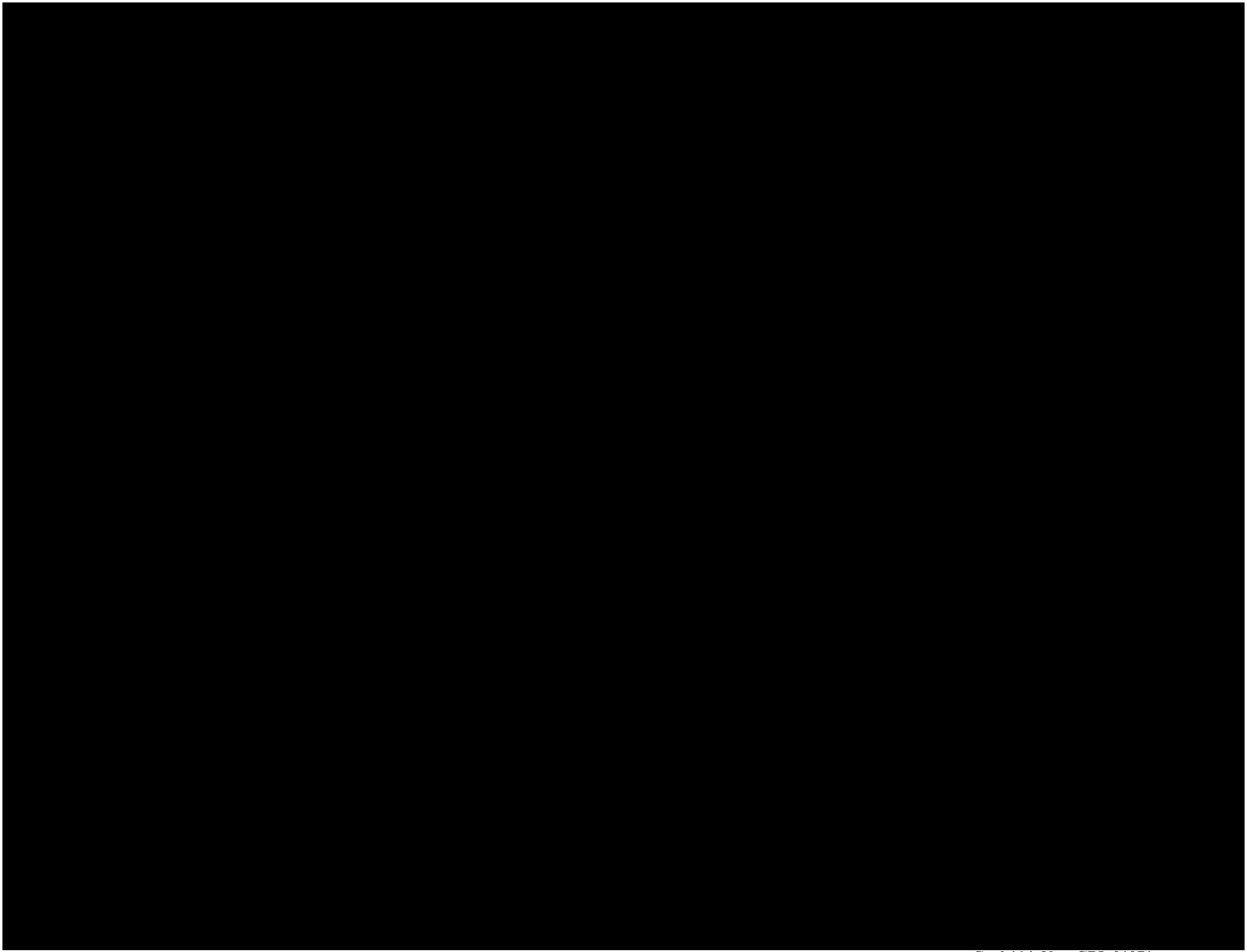


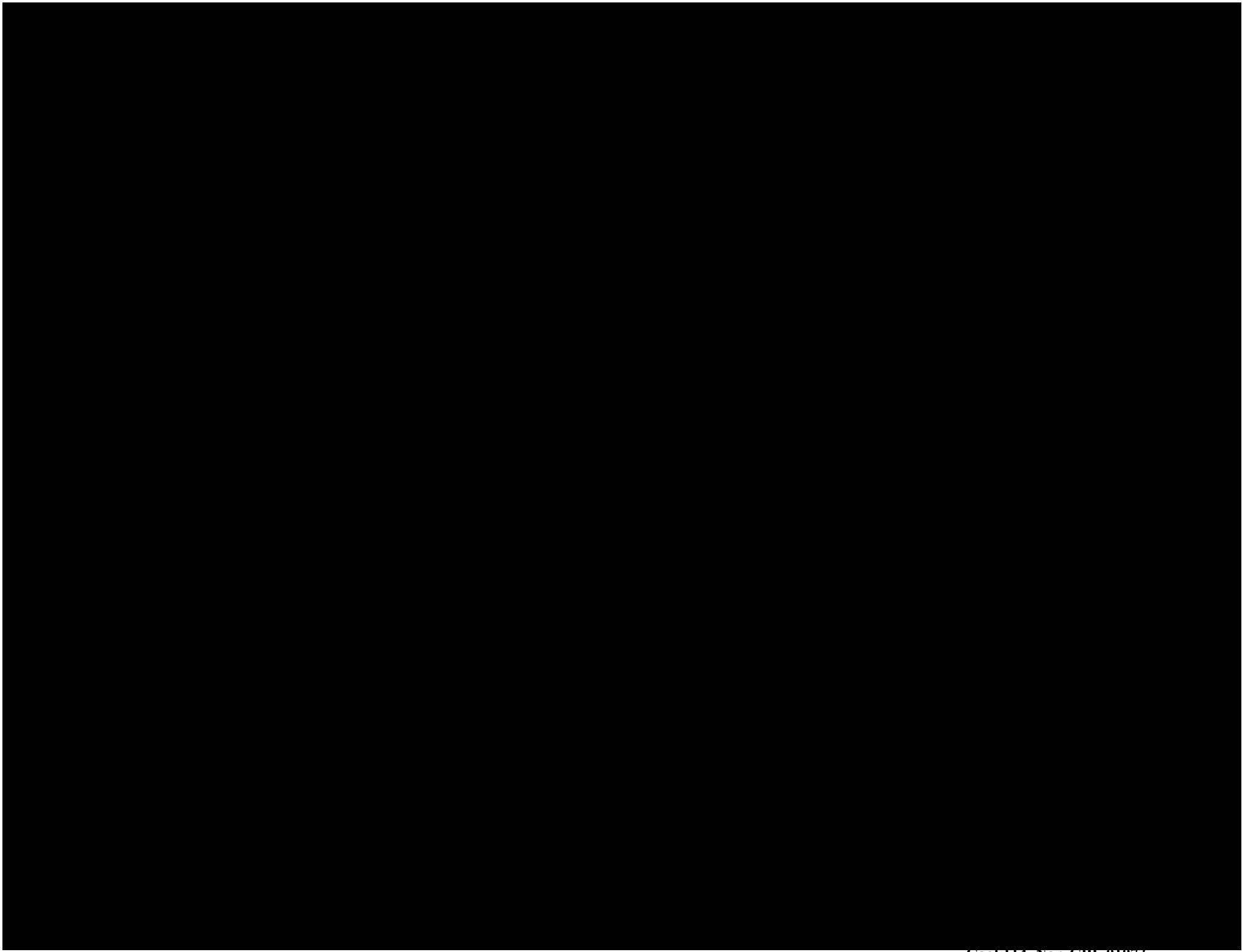


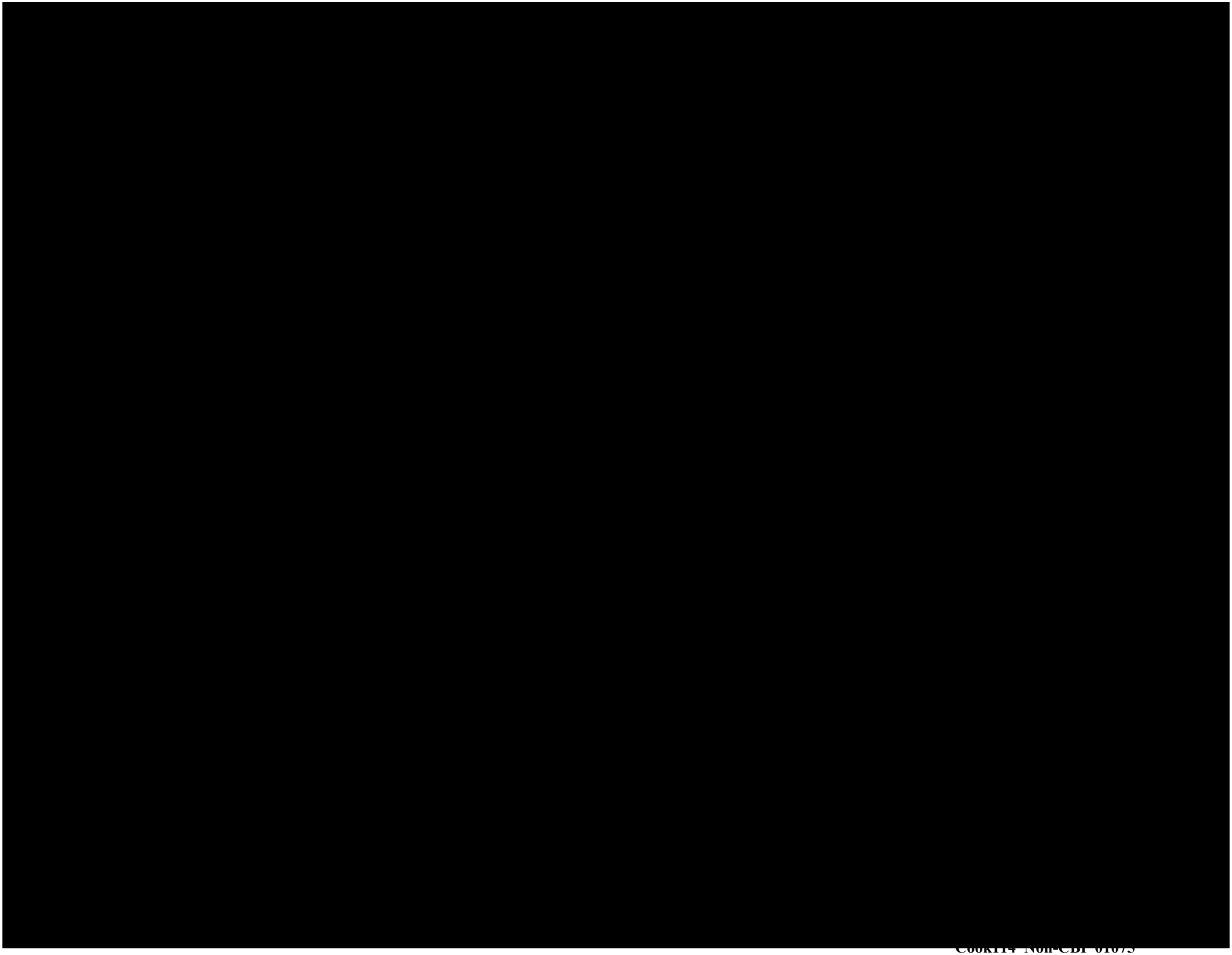


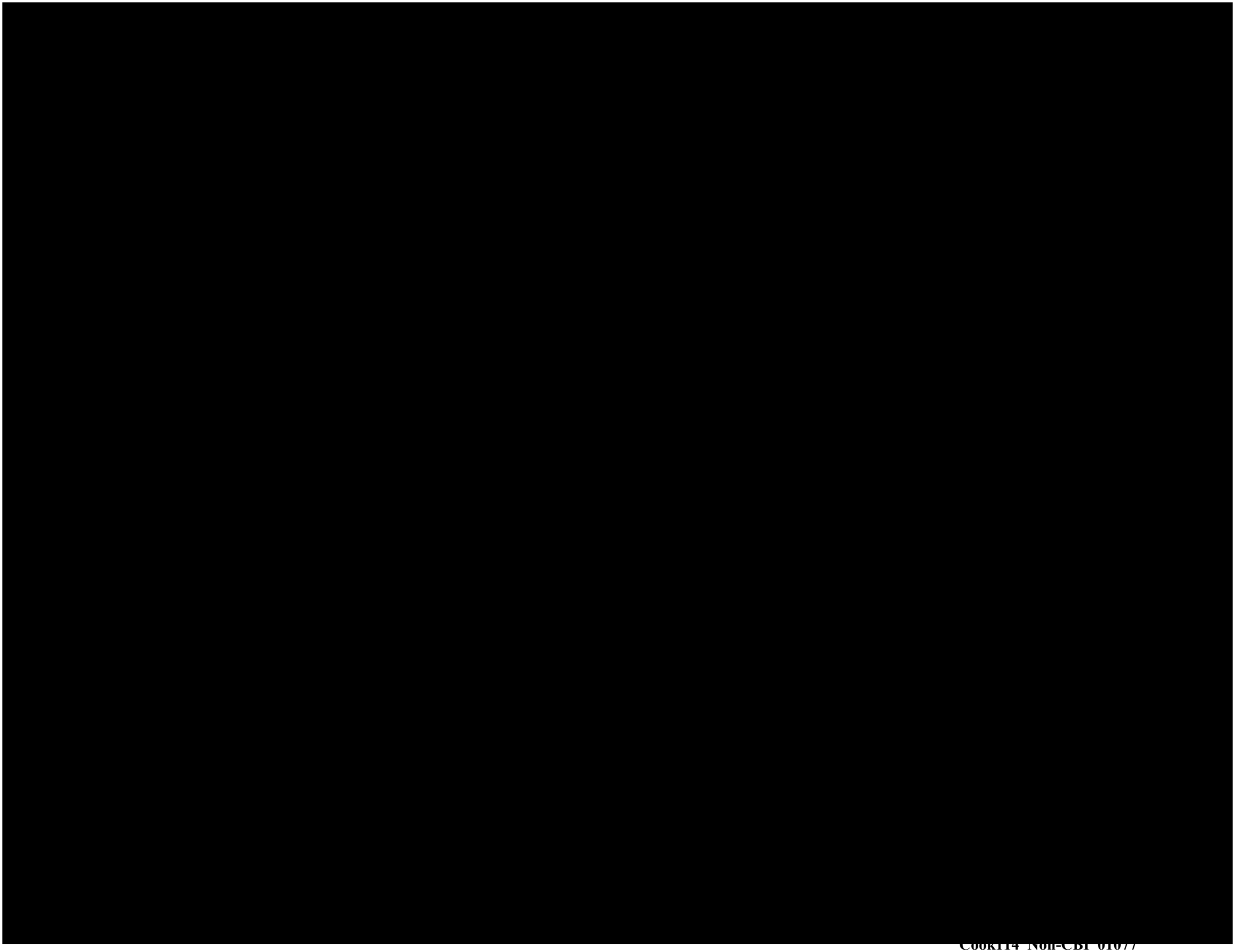


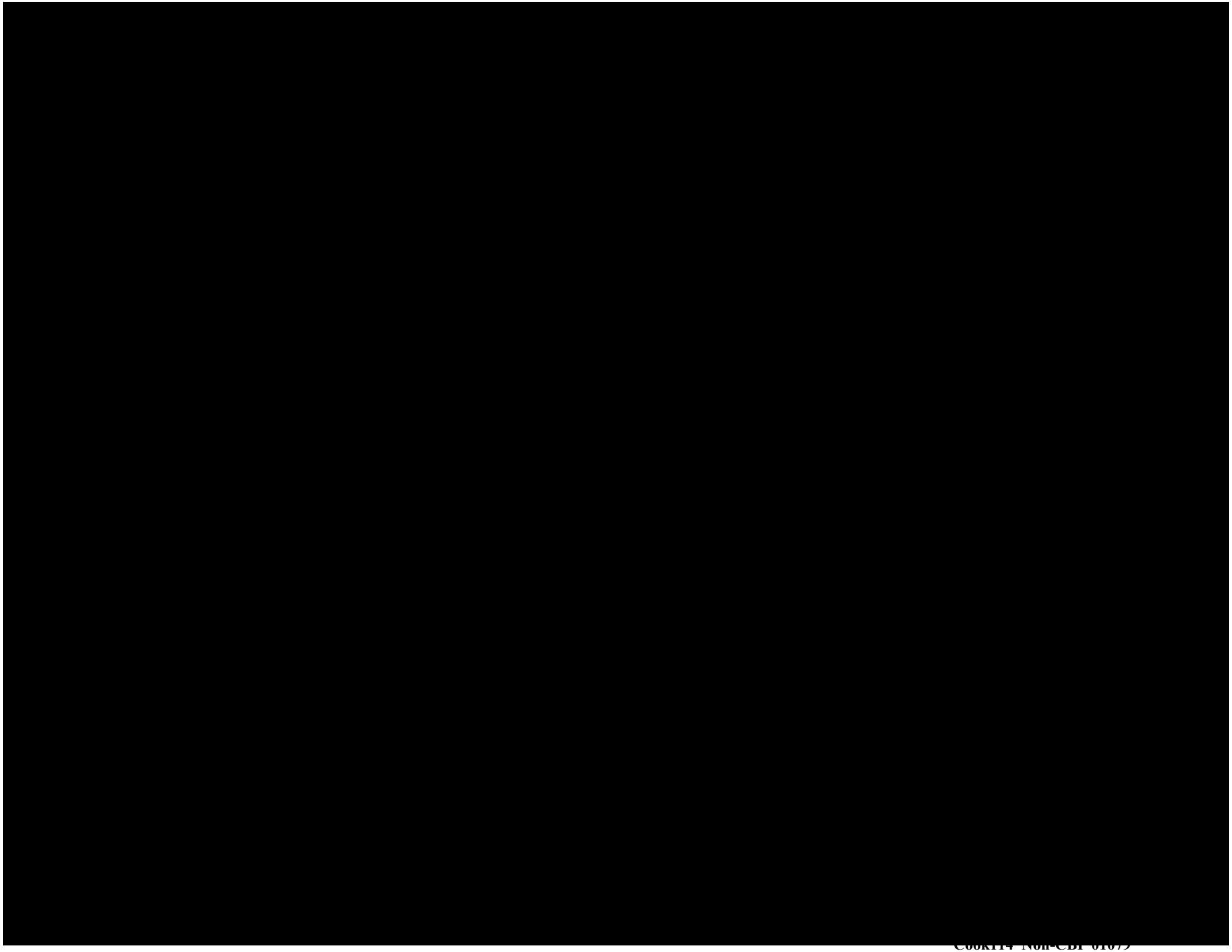


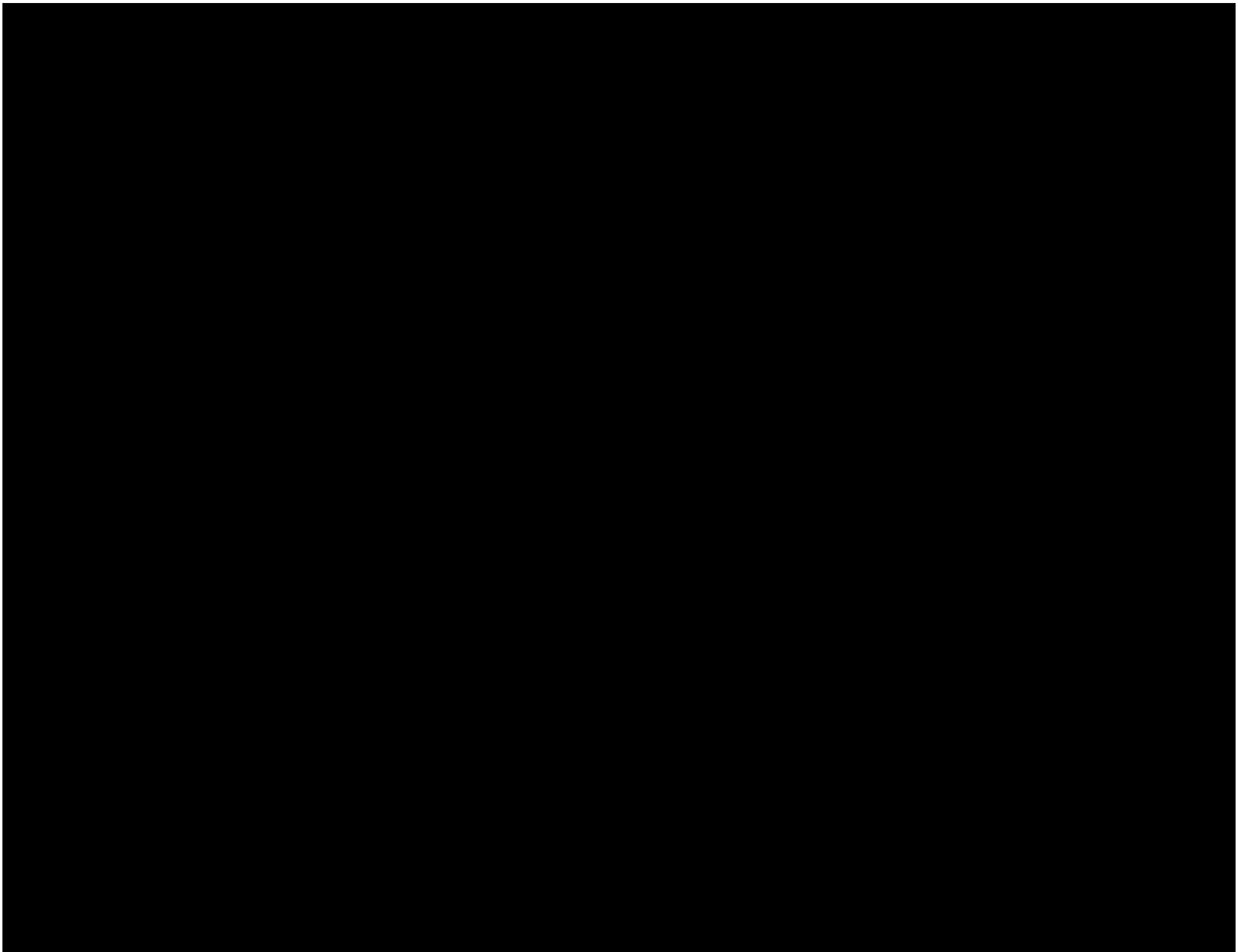


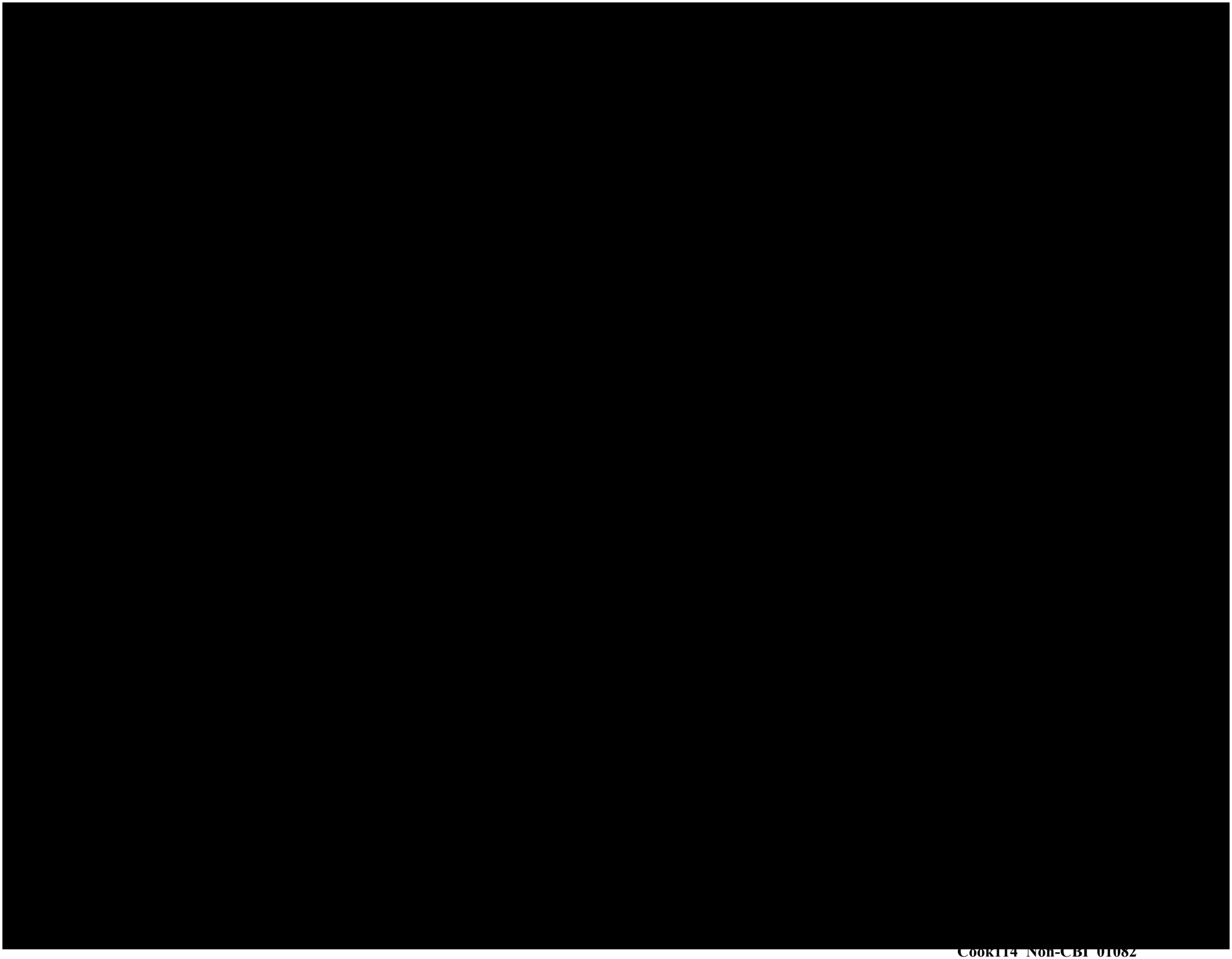


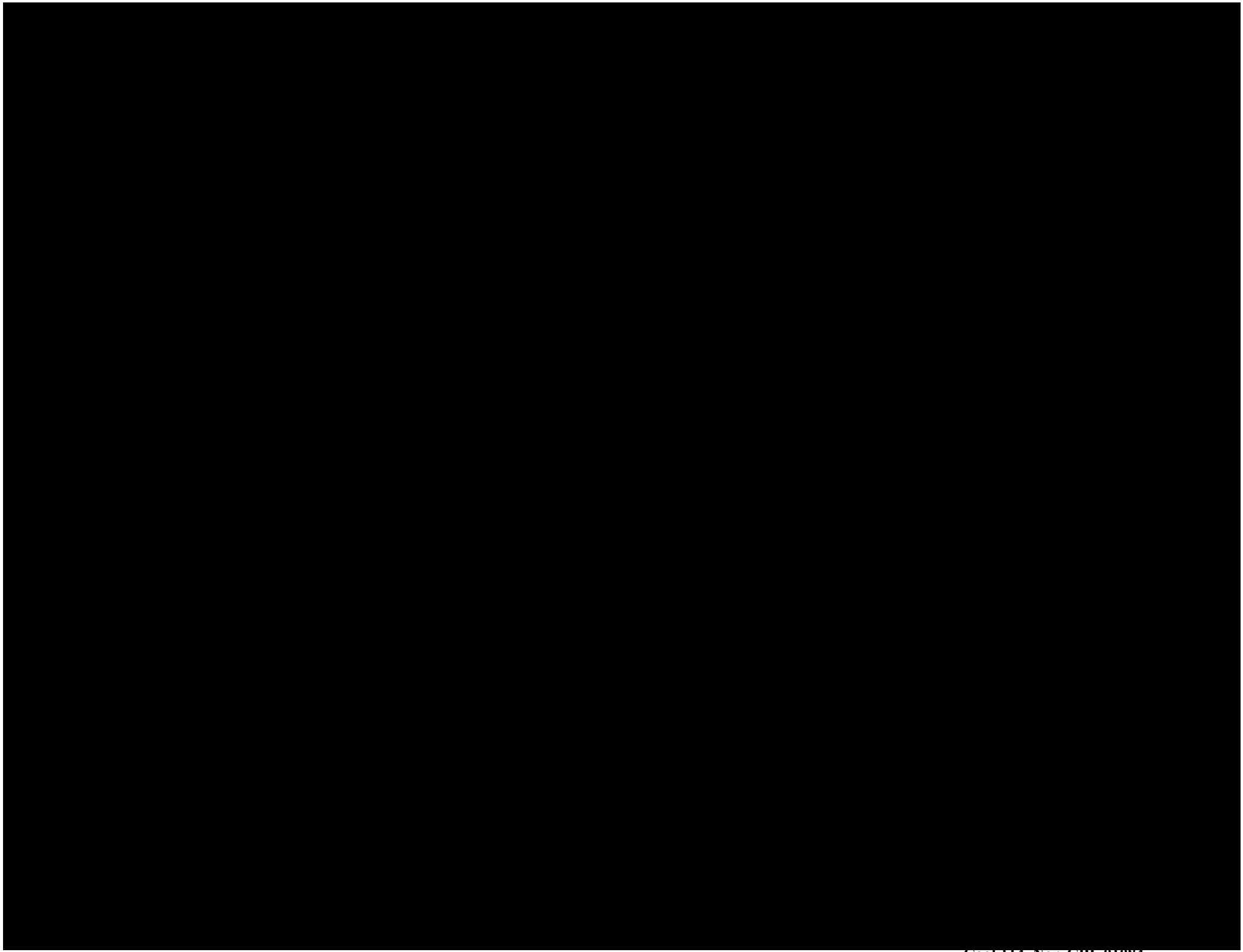


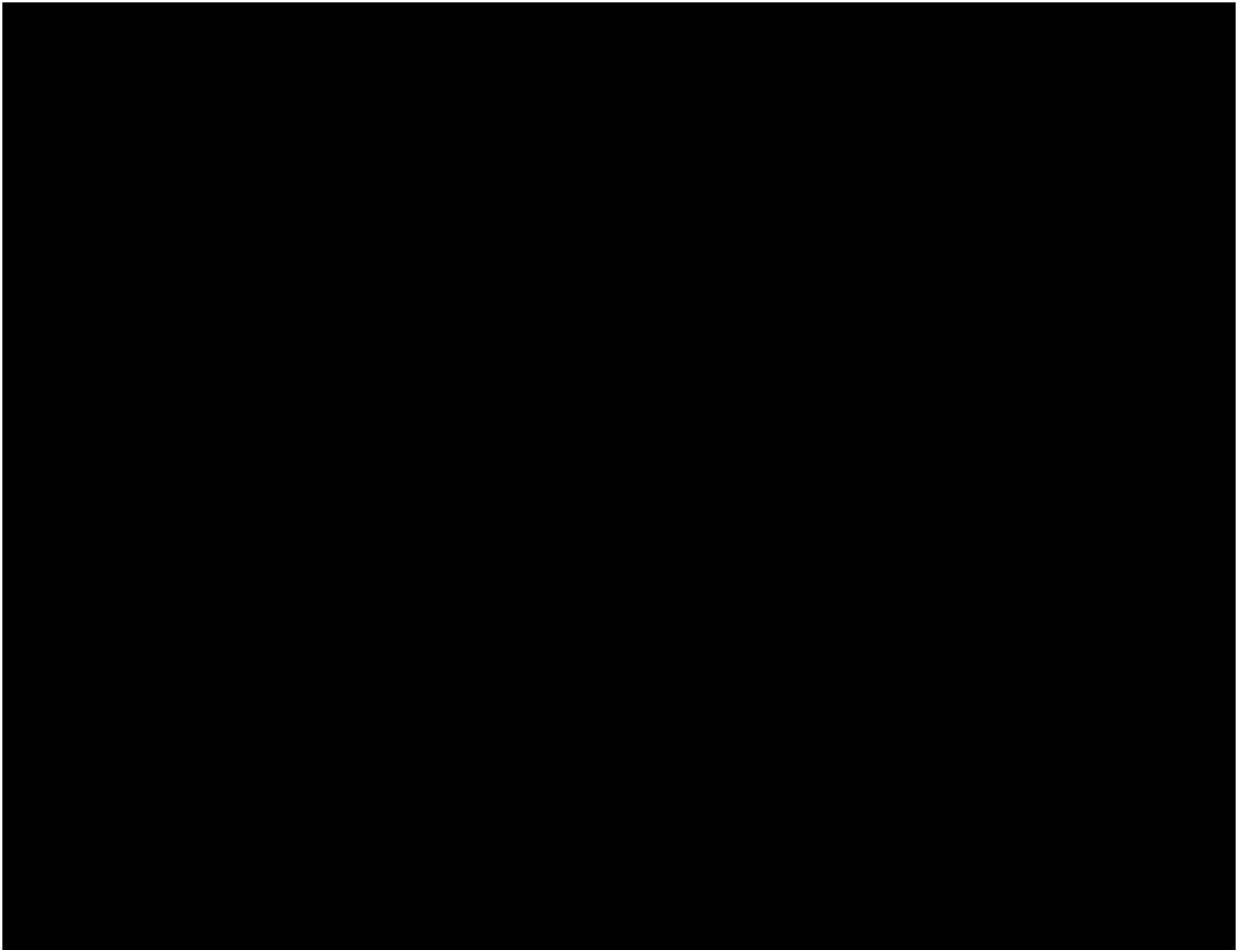


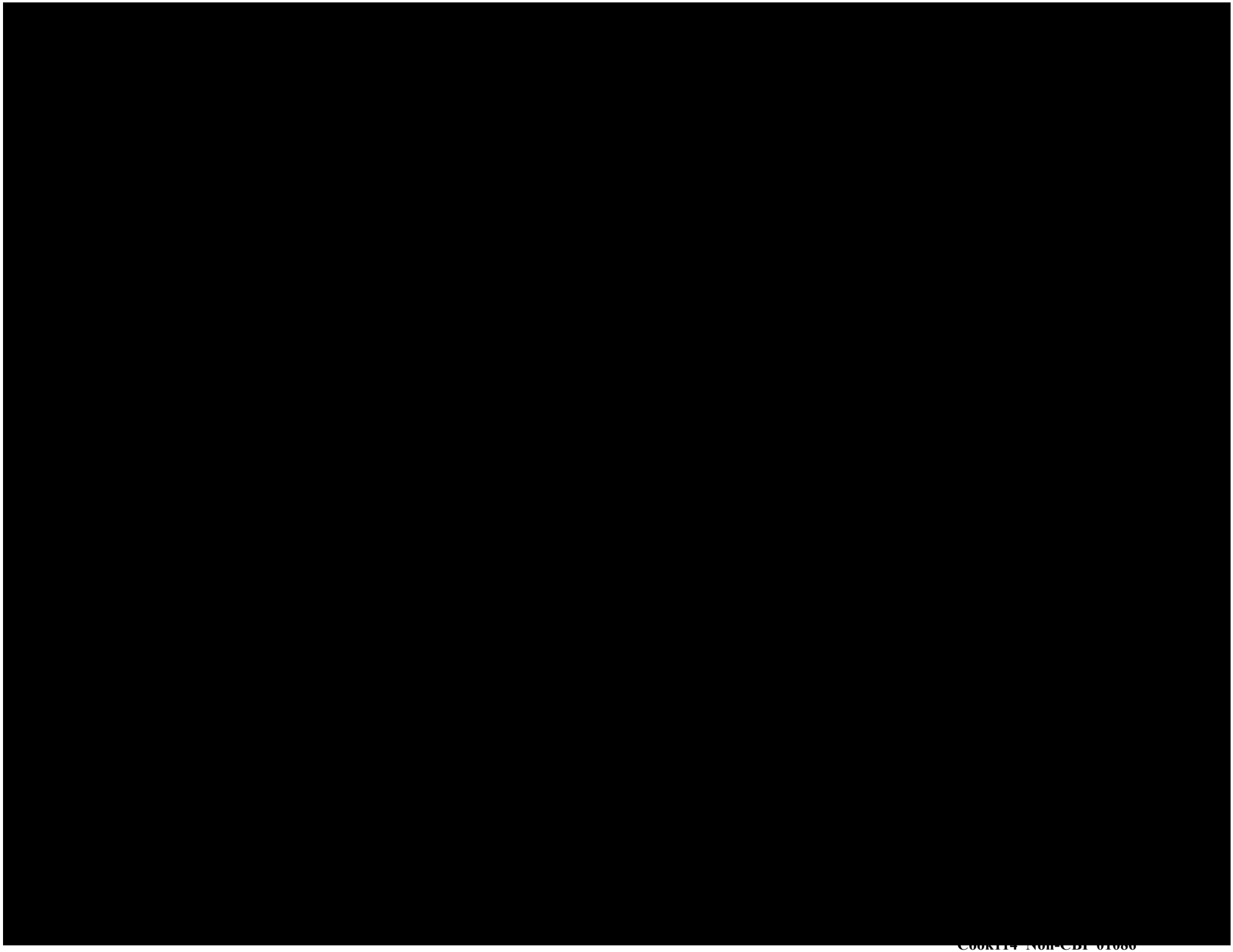


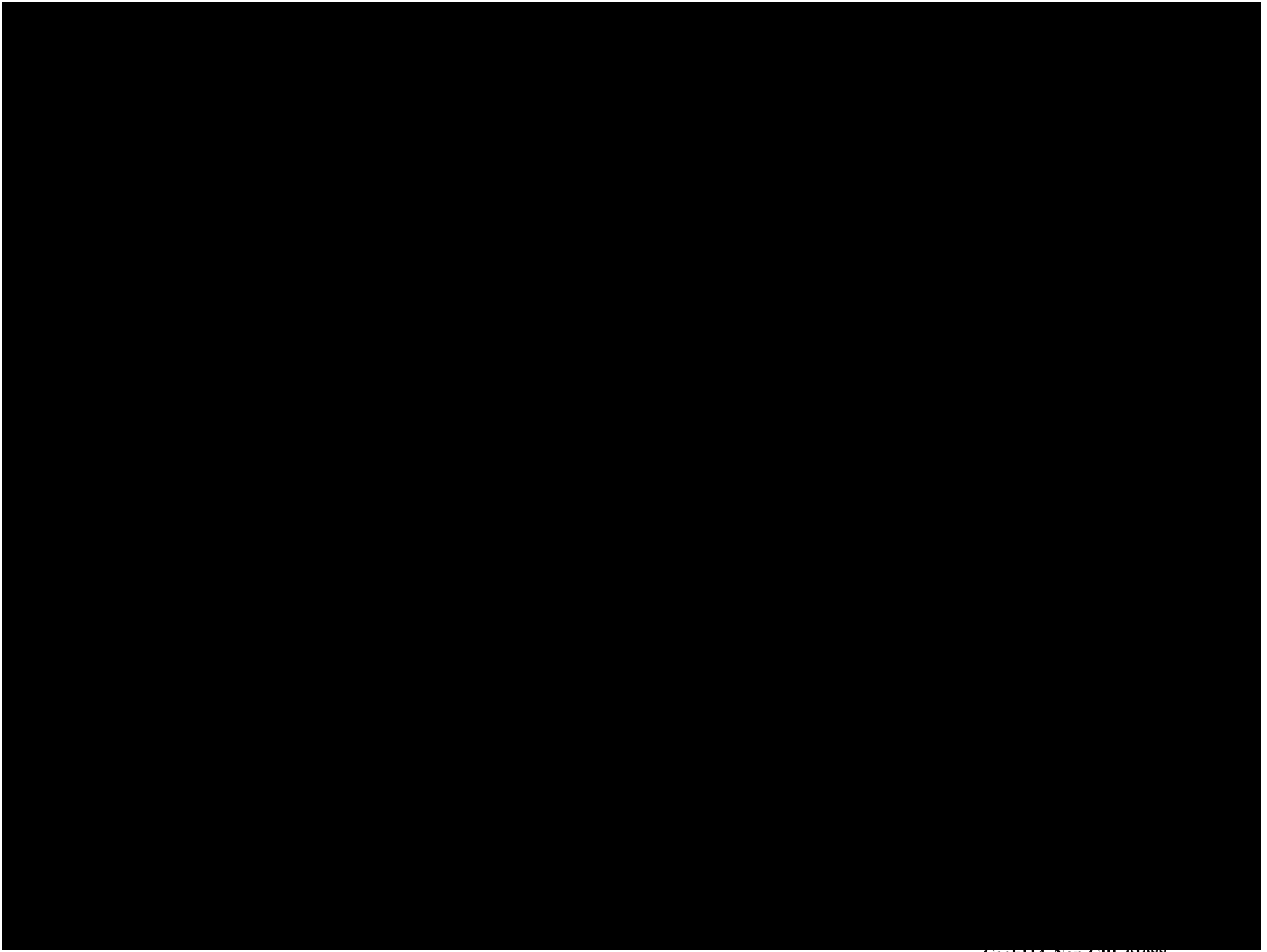


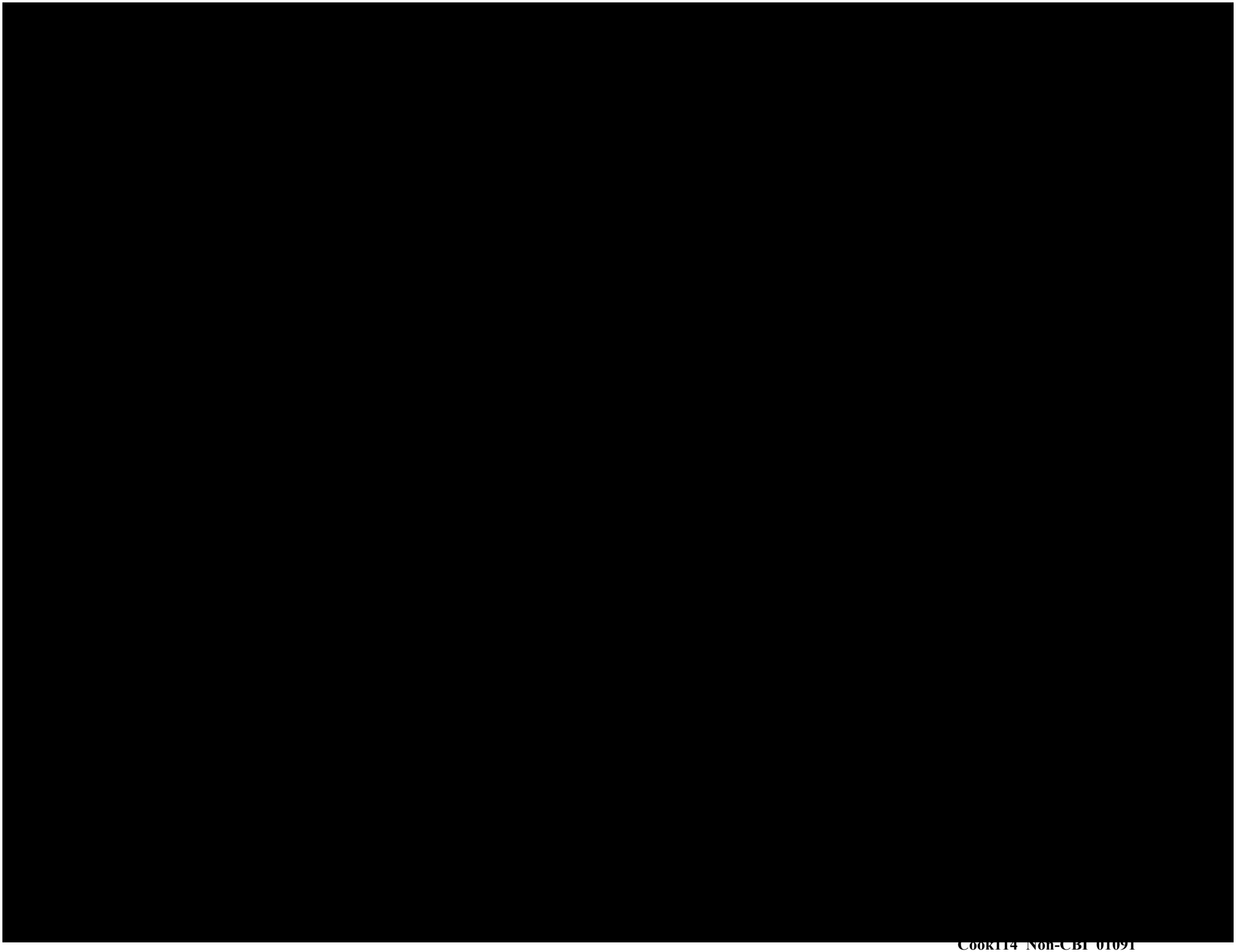


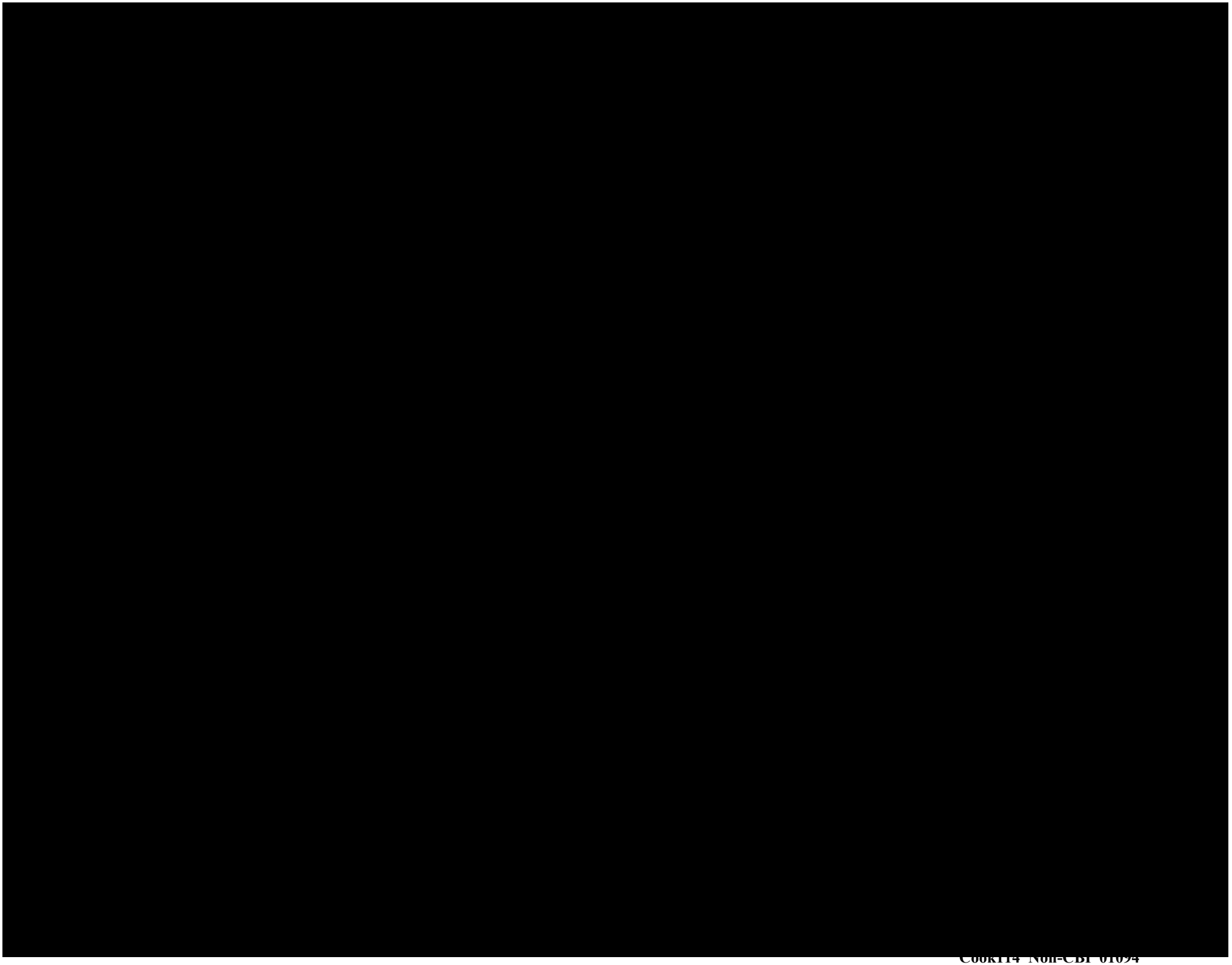


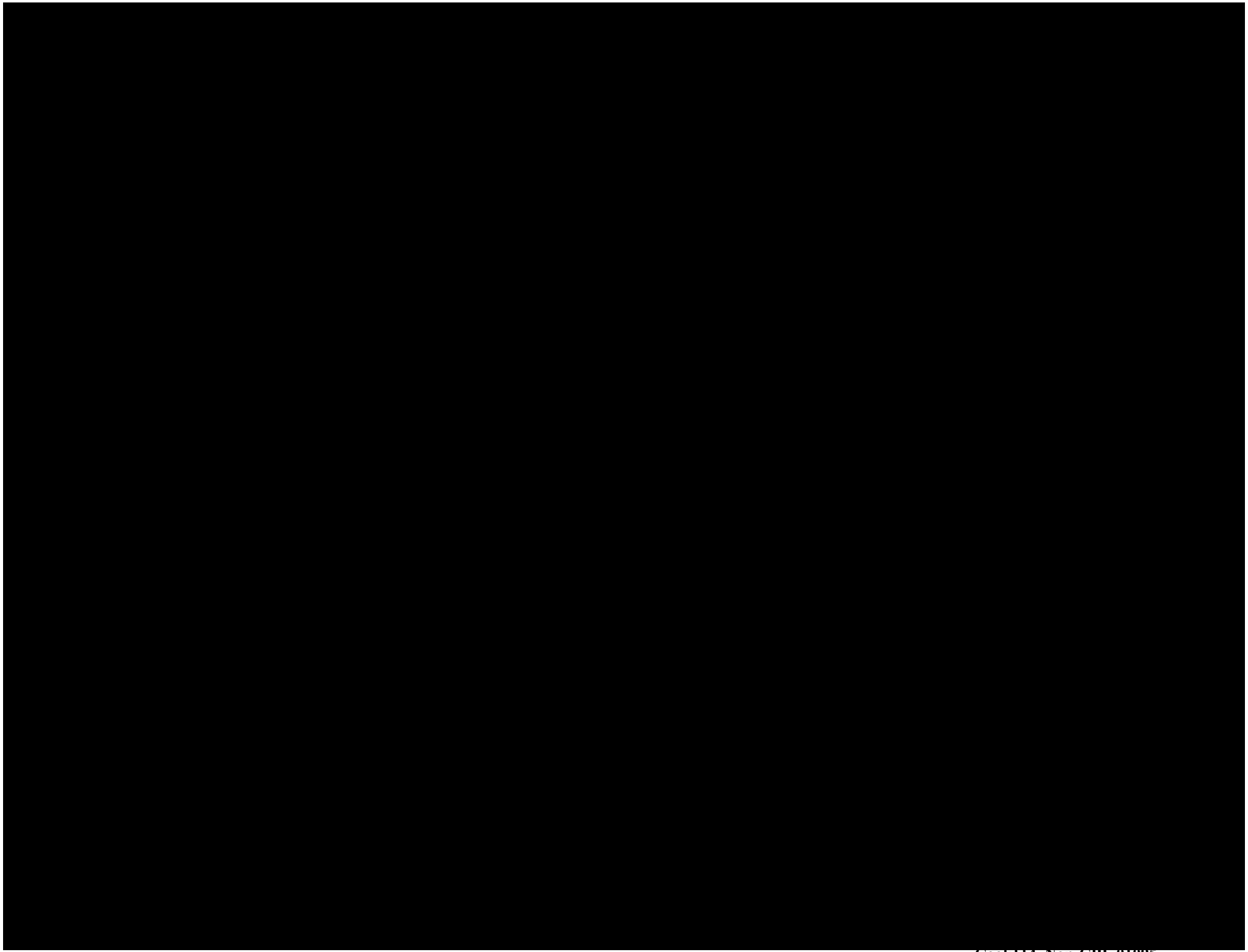


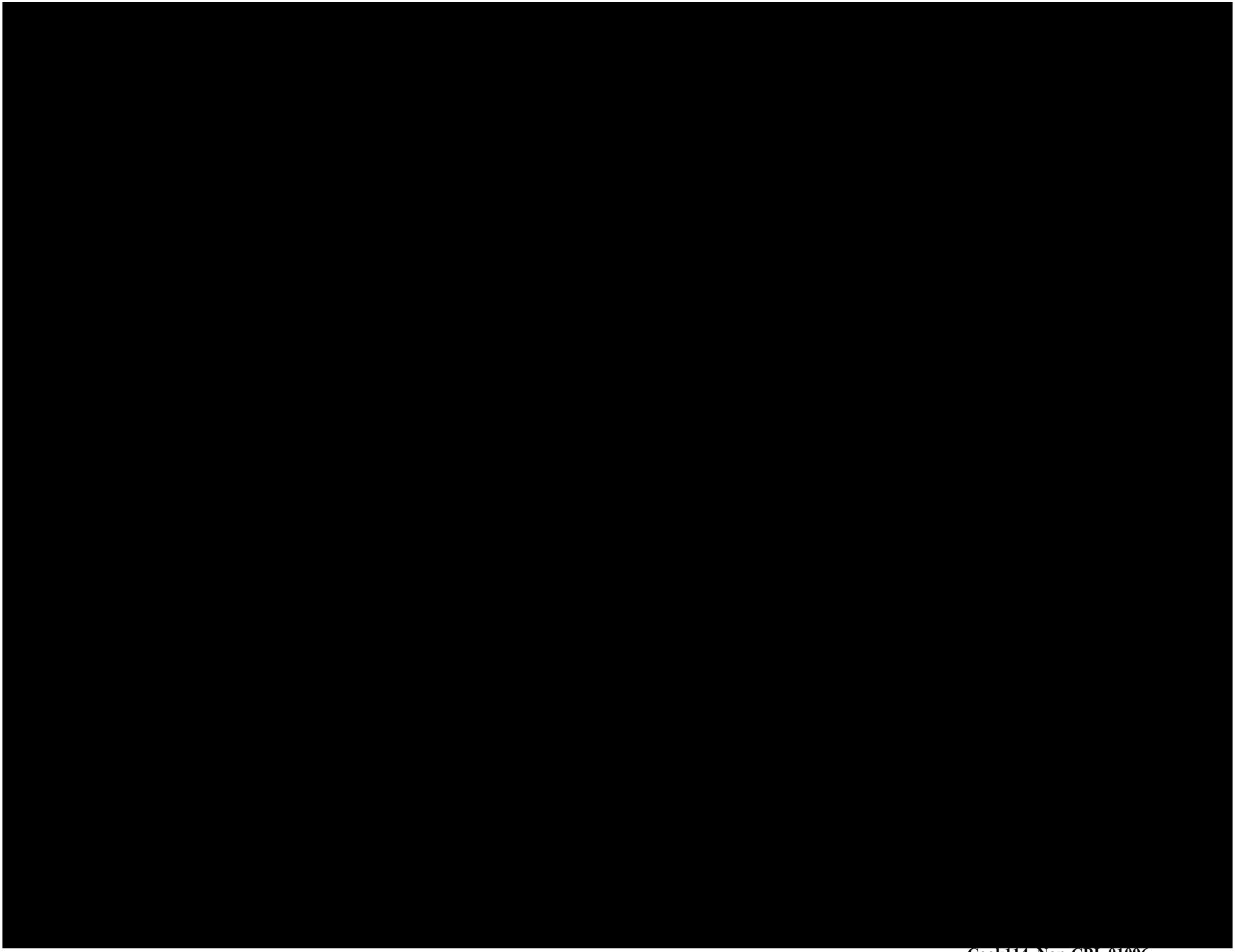


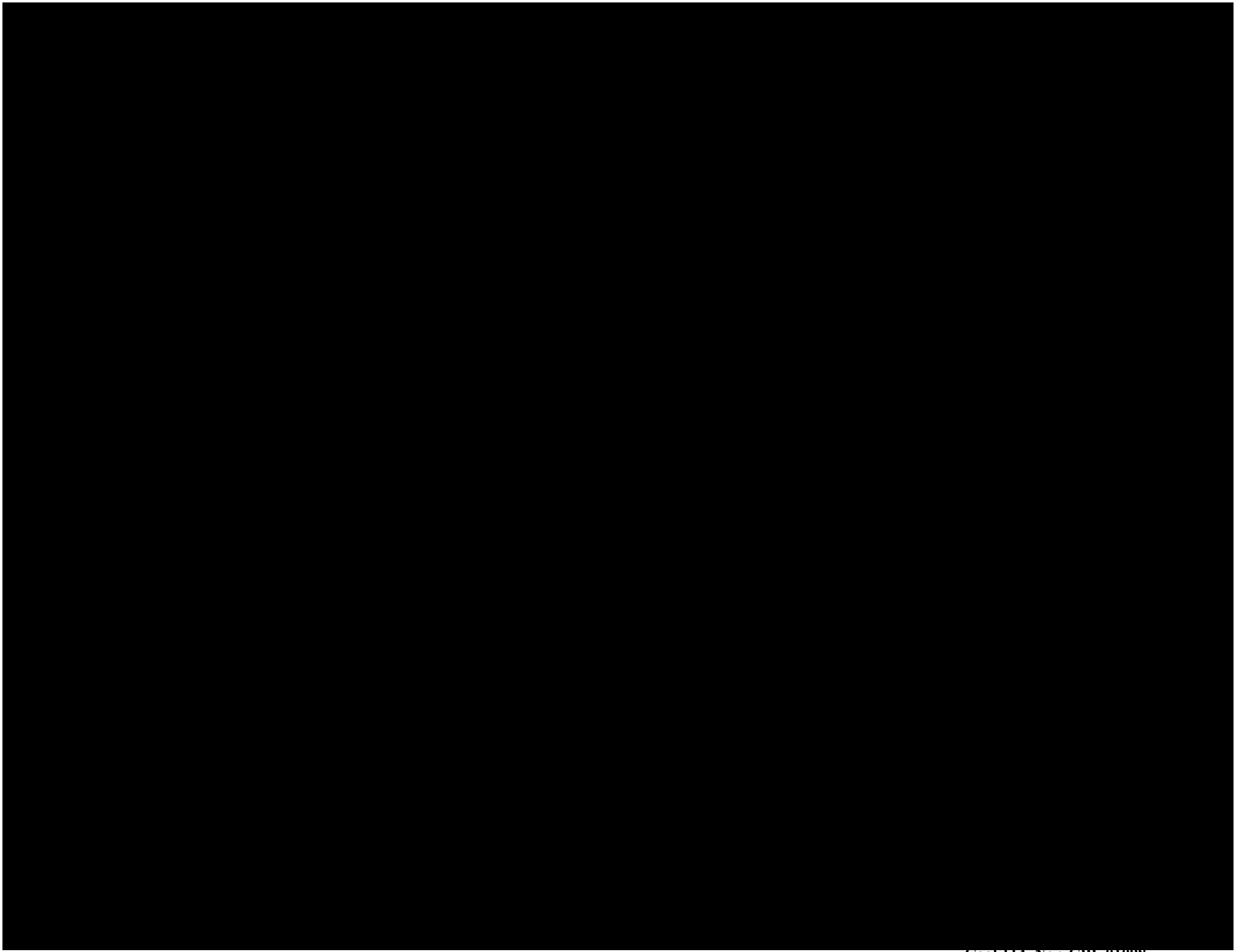


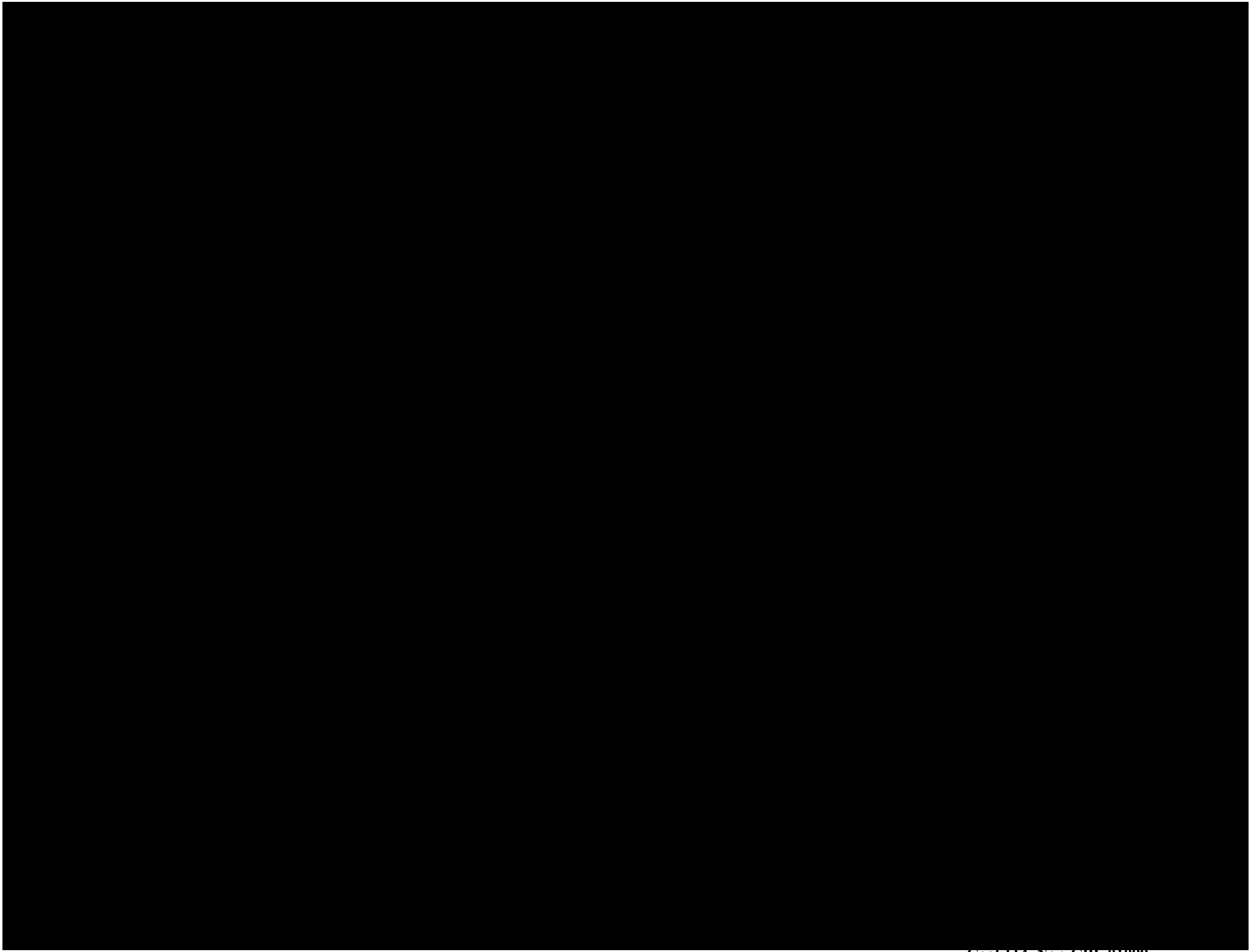


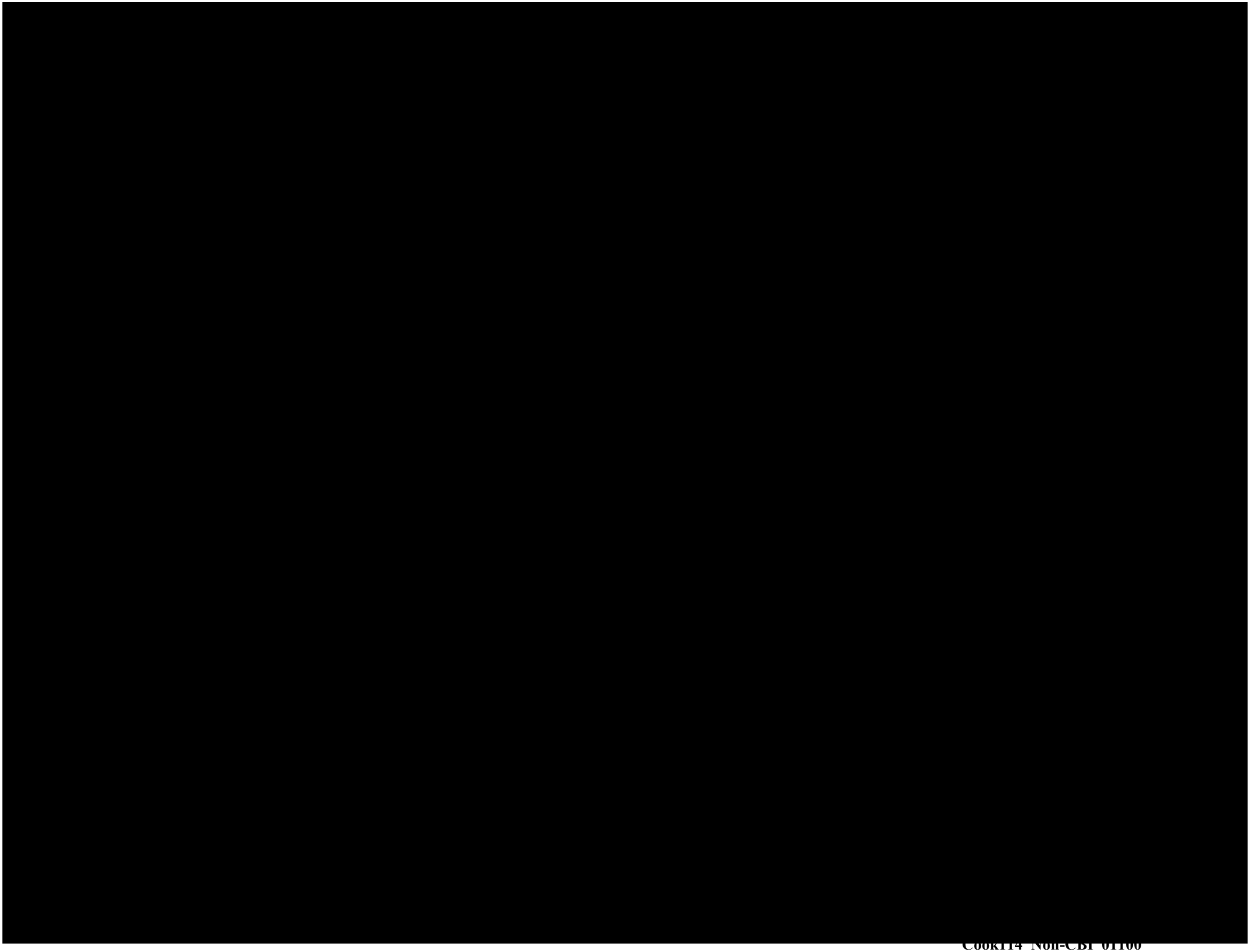


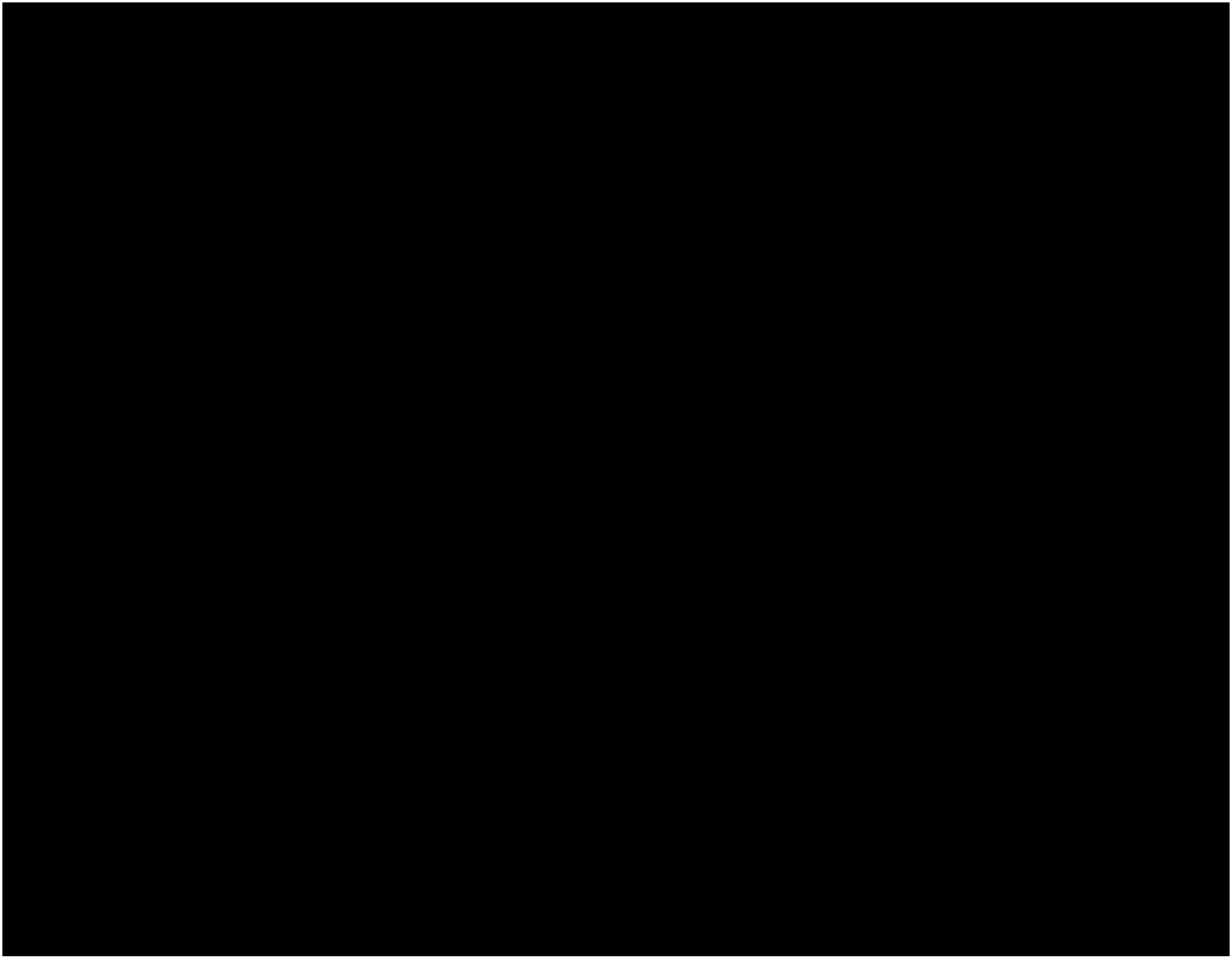


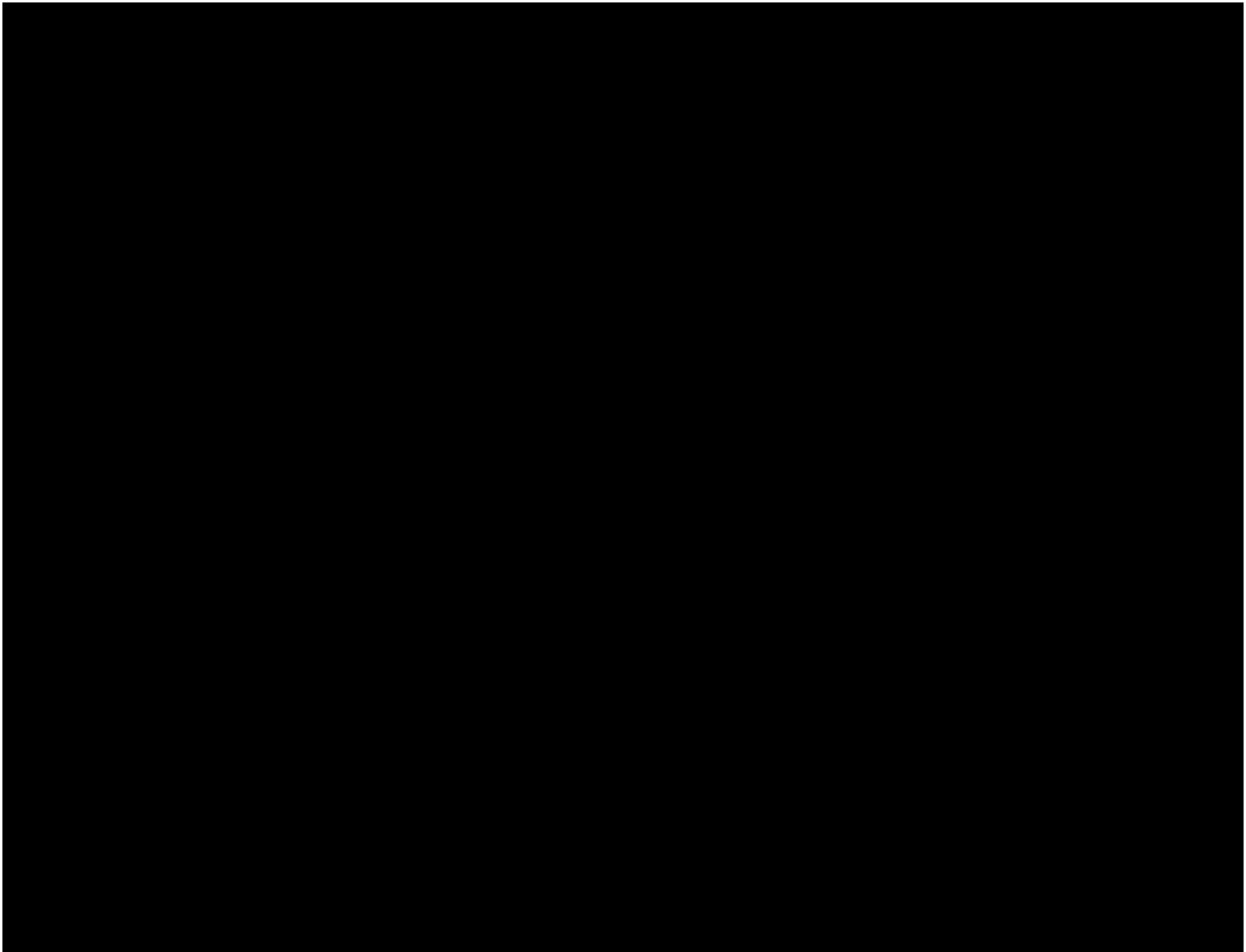


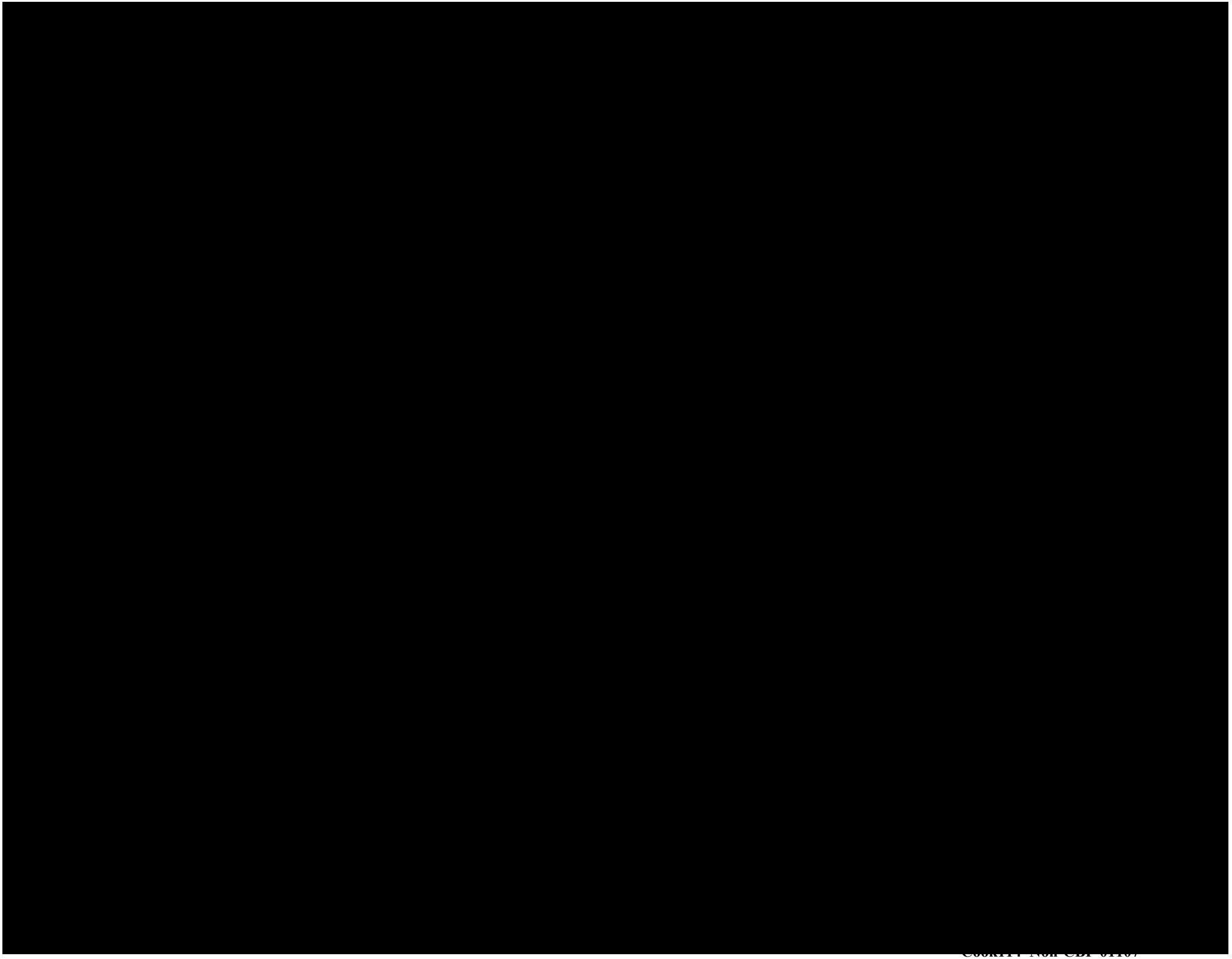


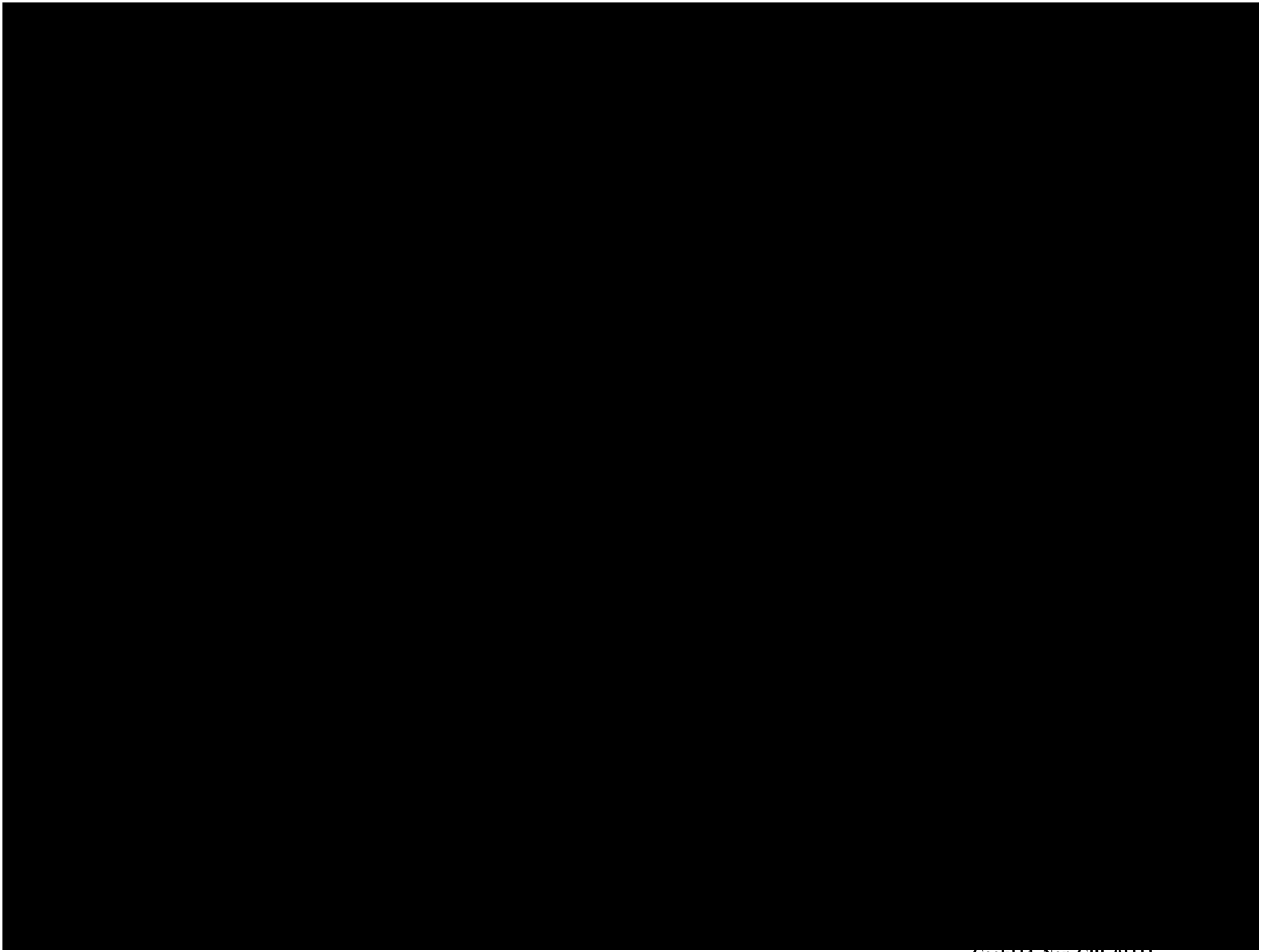


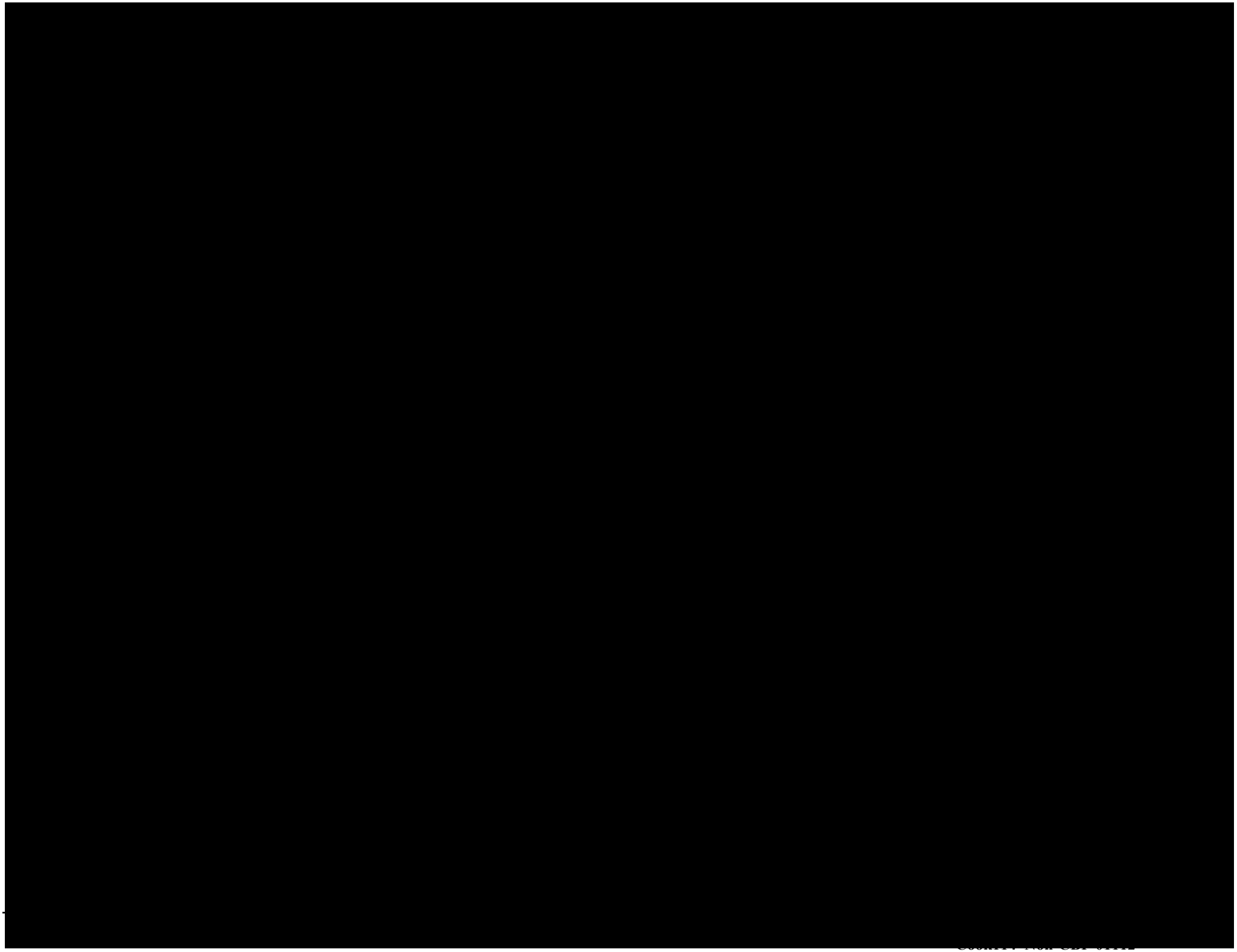


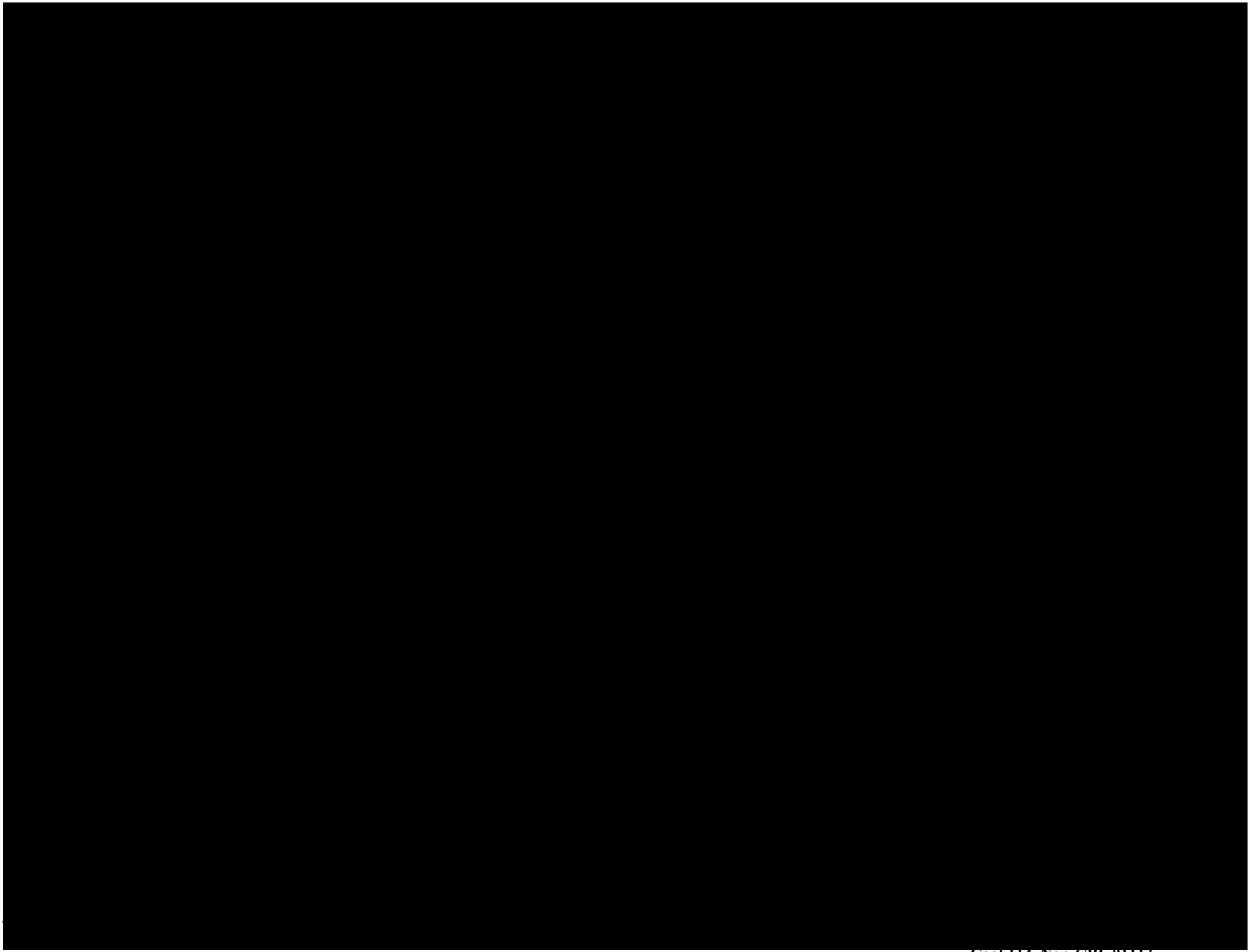


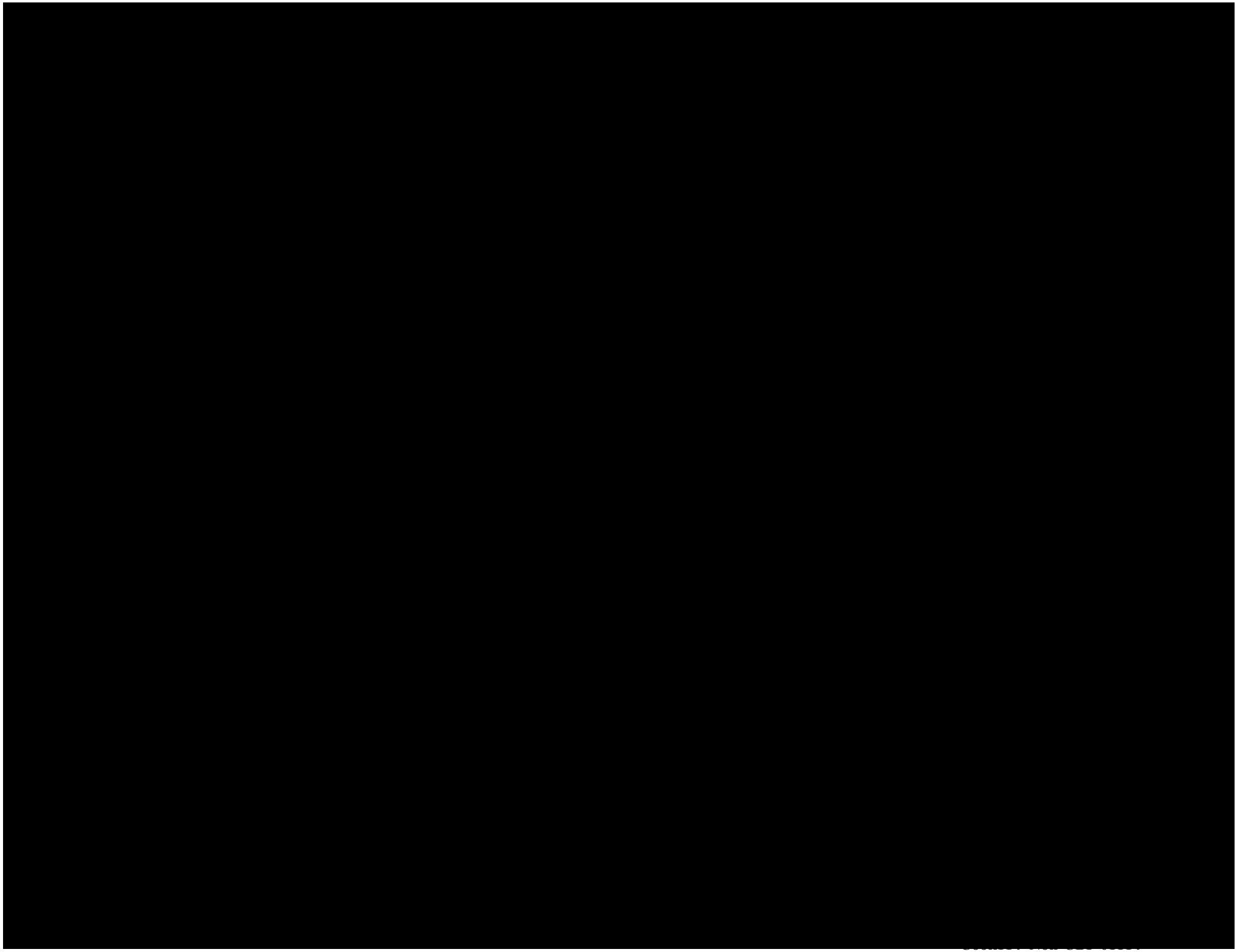


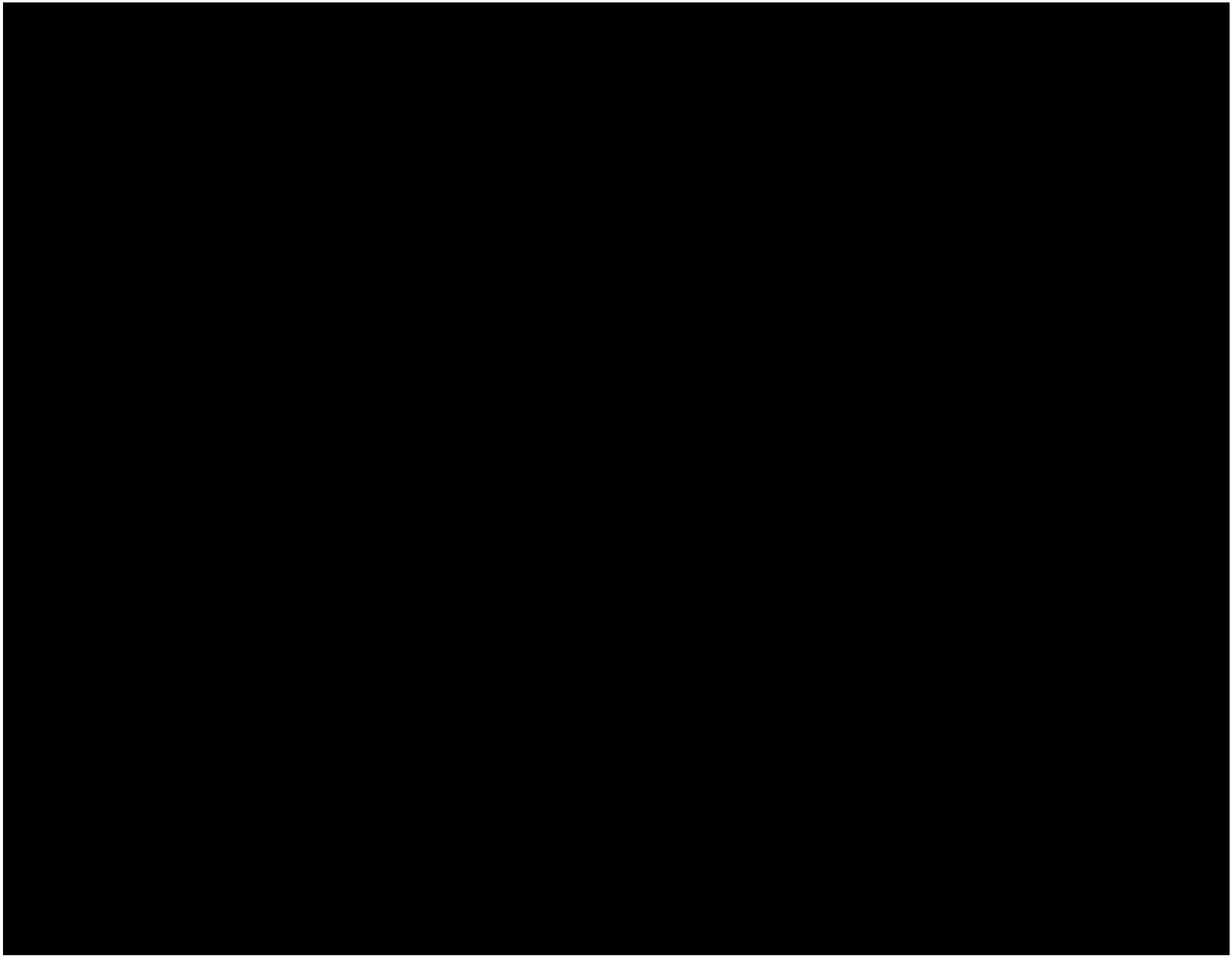


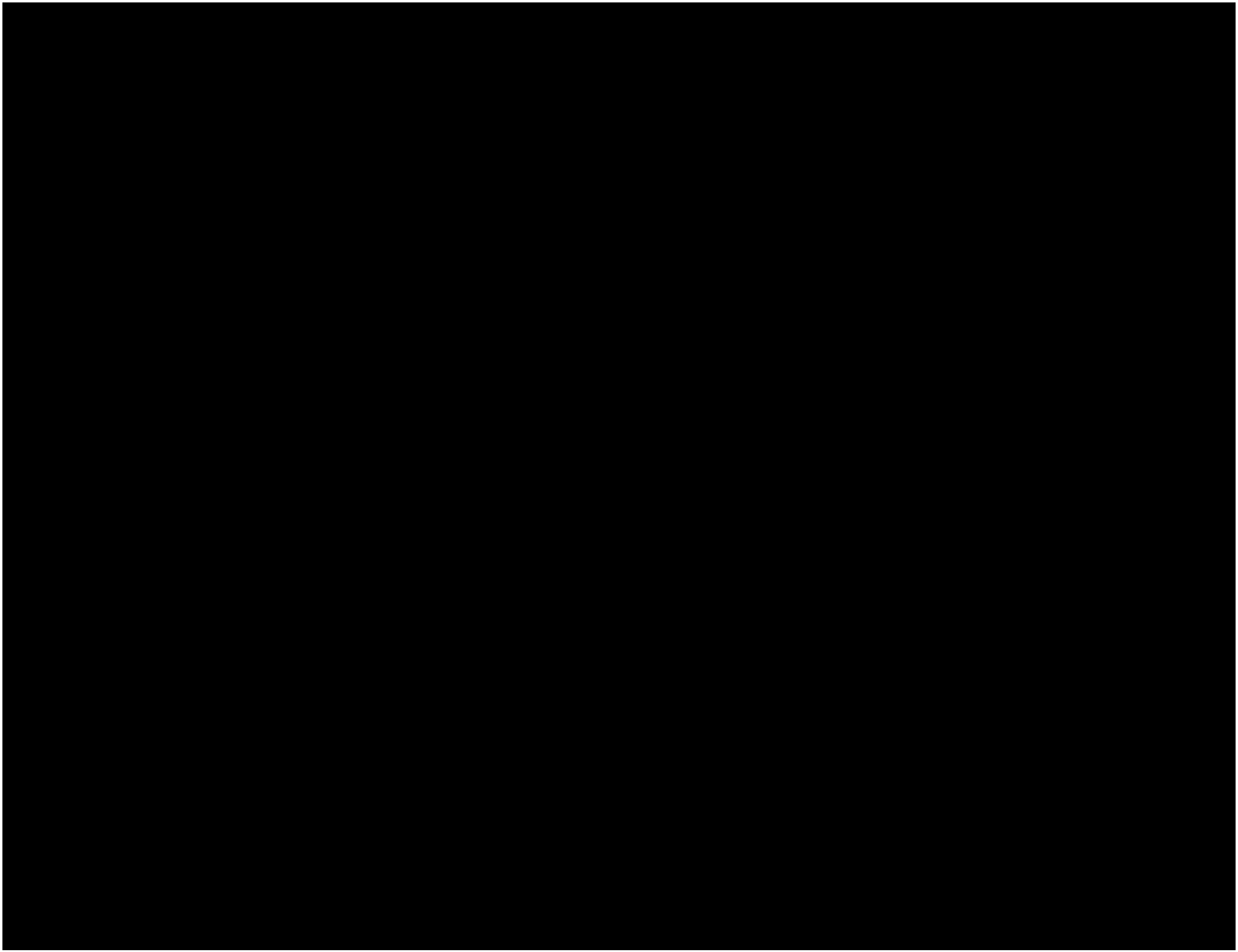


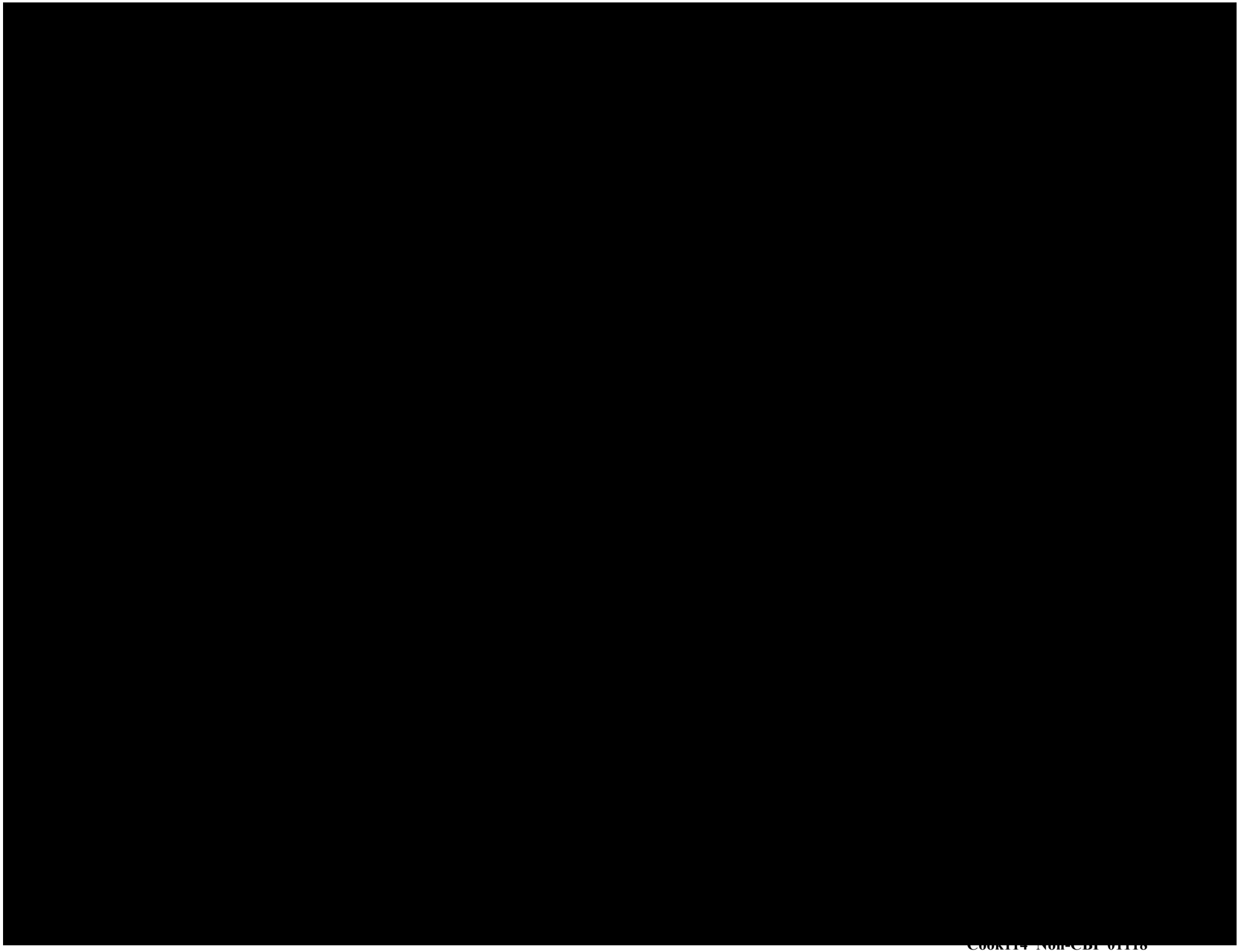


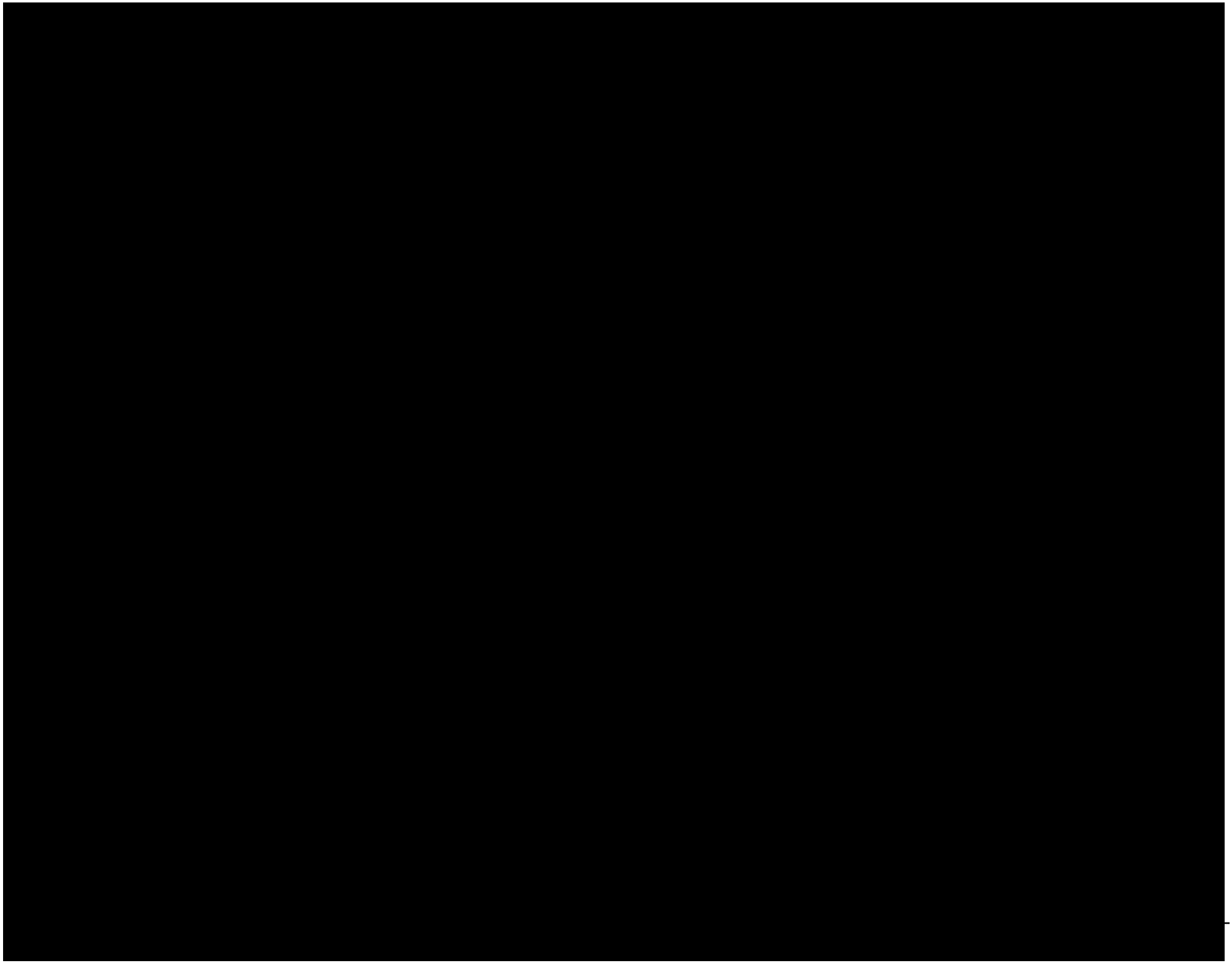


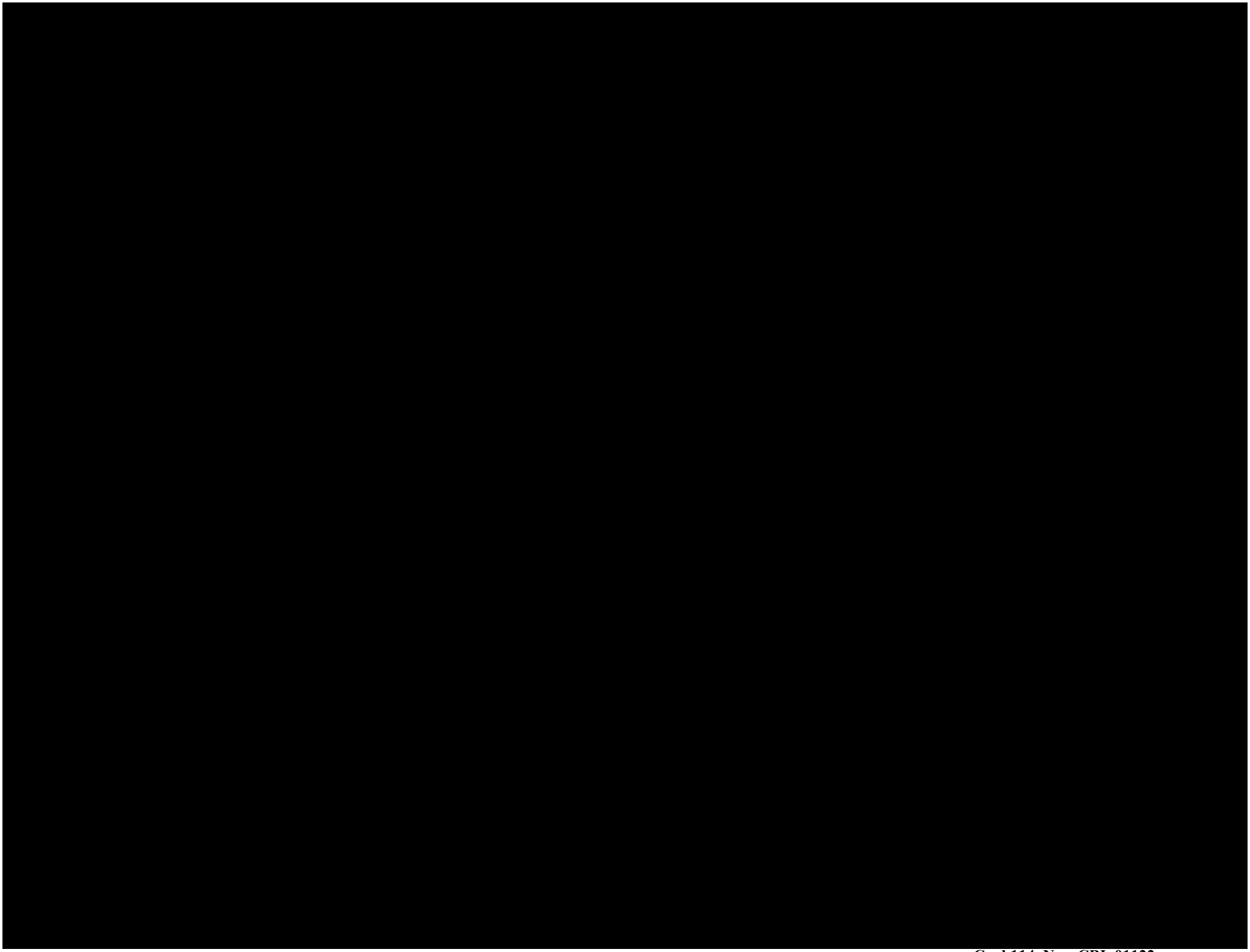


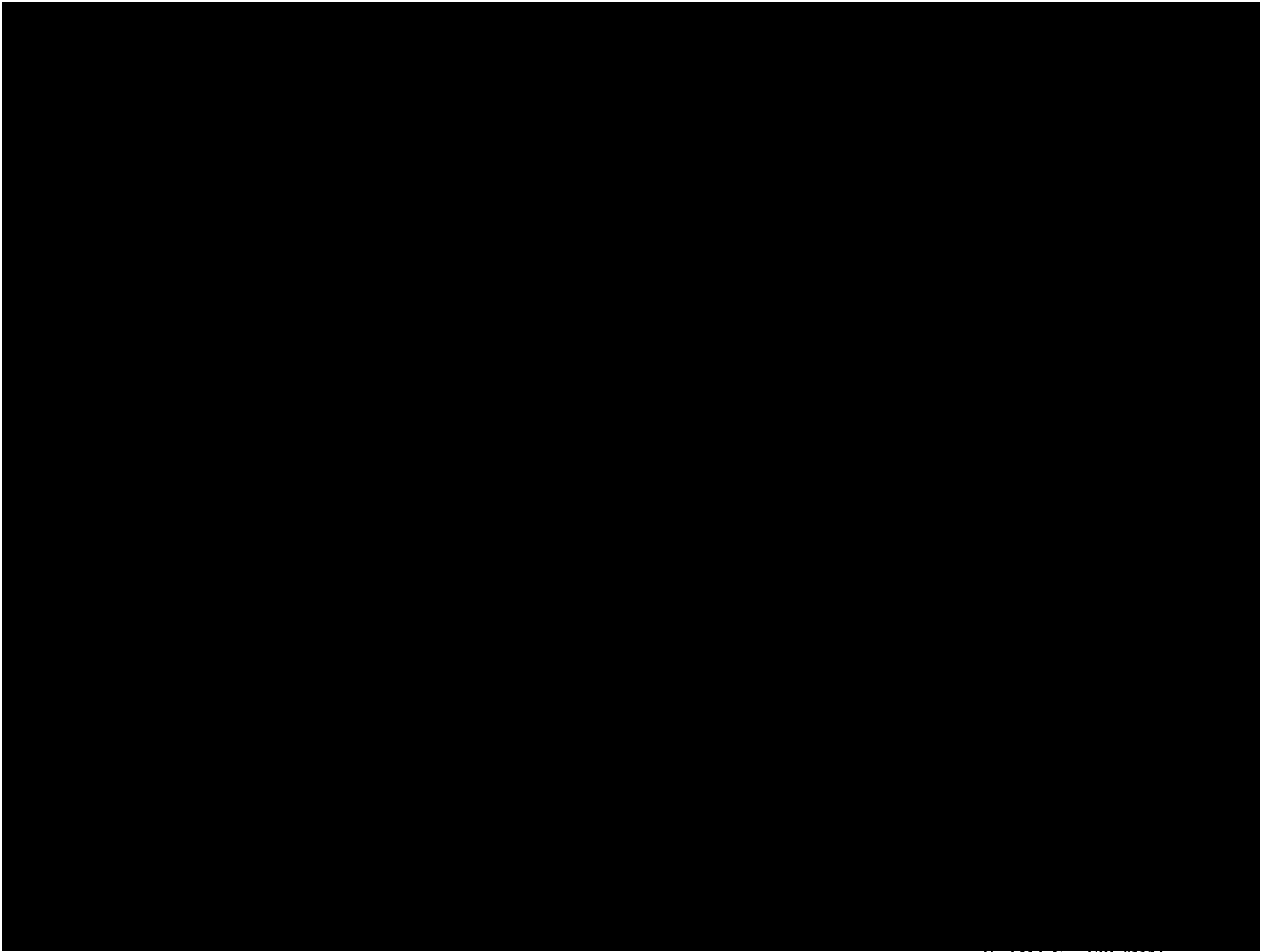


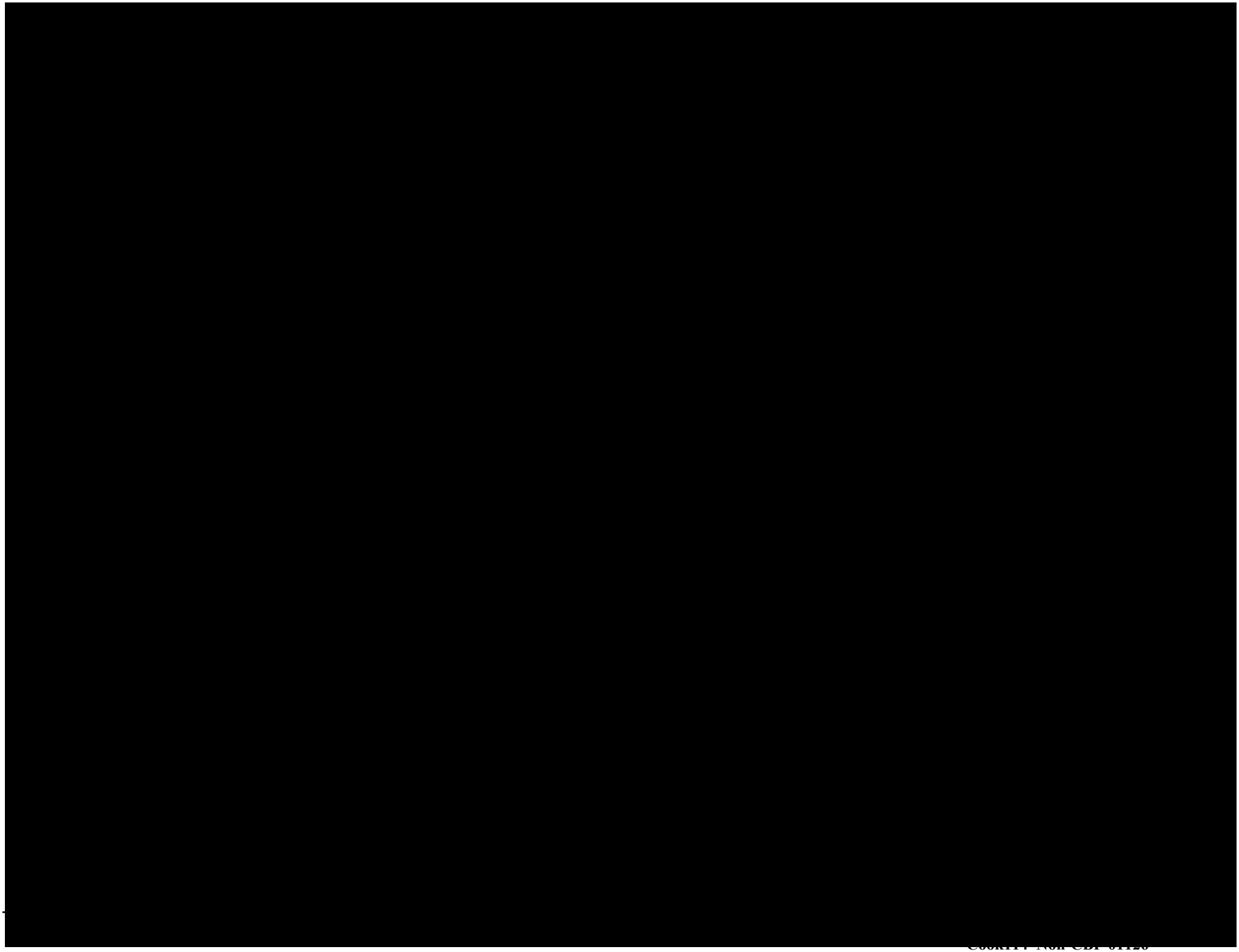


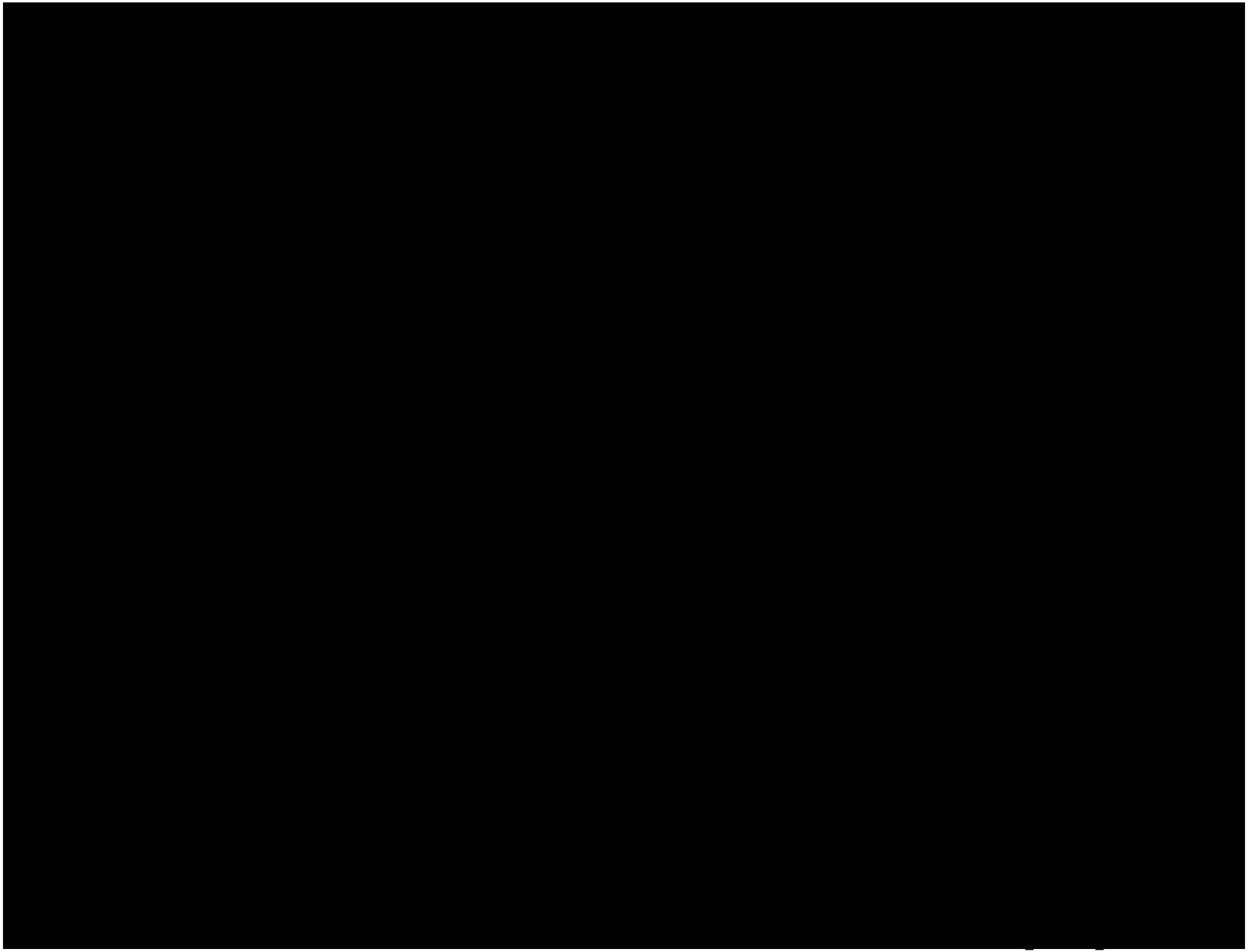












SCV Test #2

Sterilizers S8

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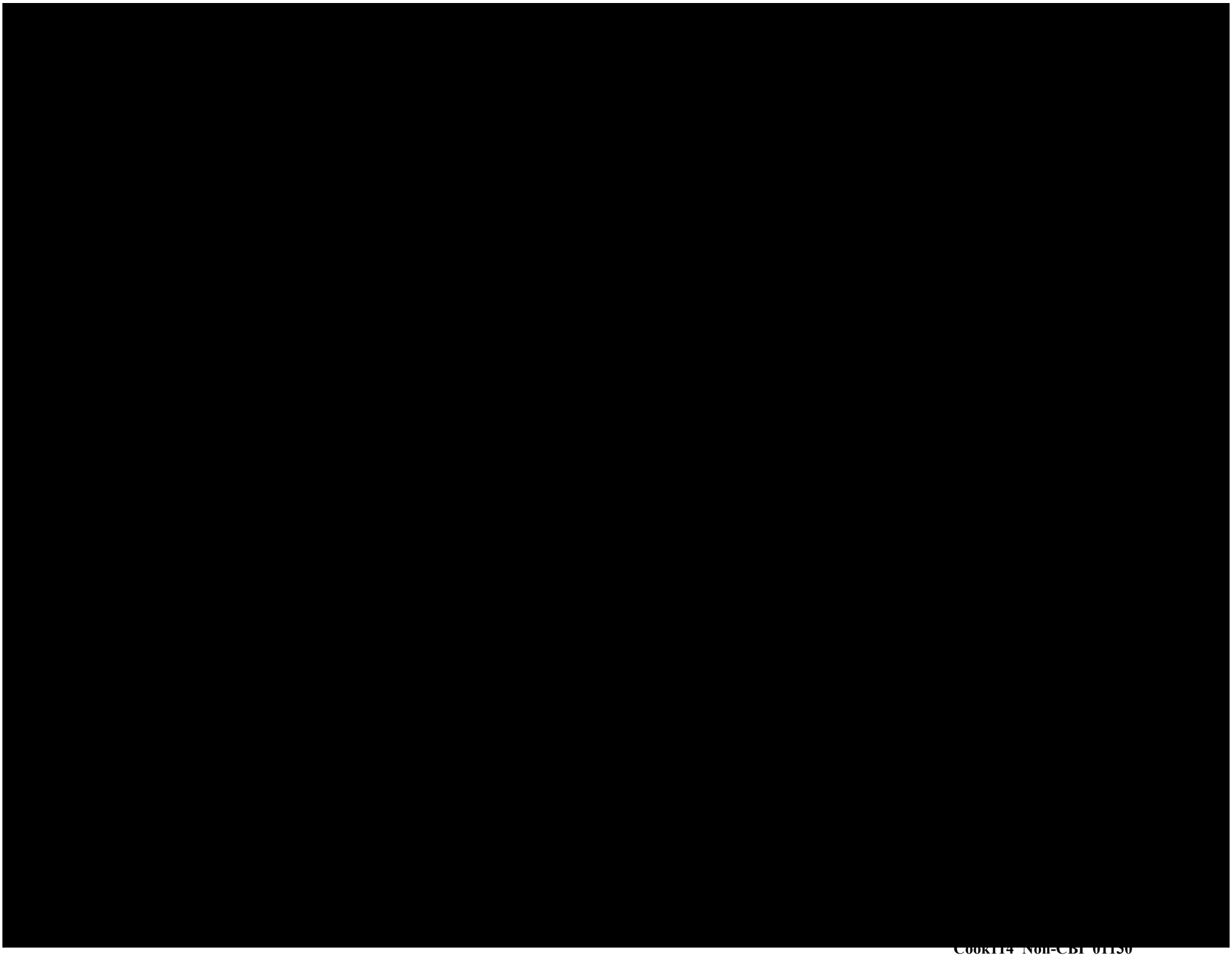

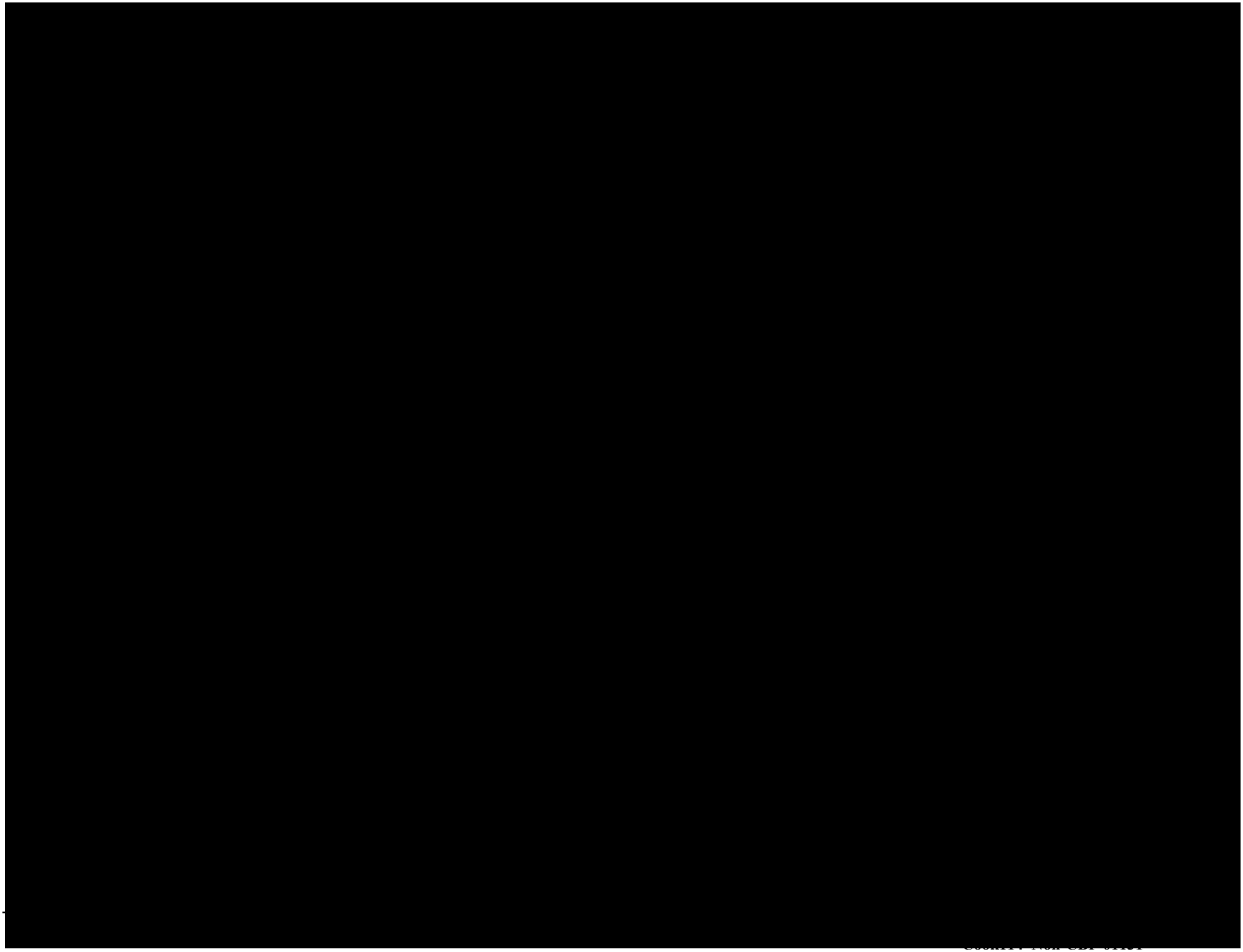

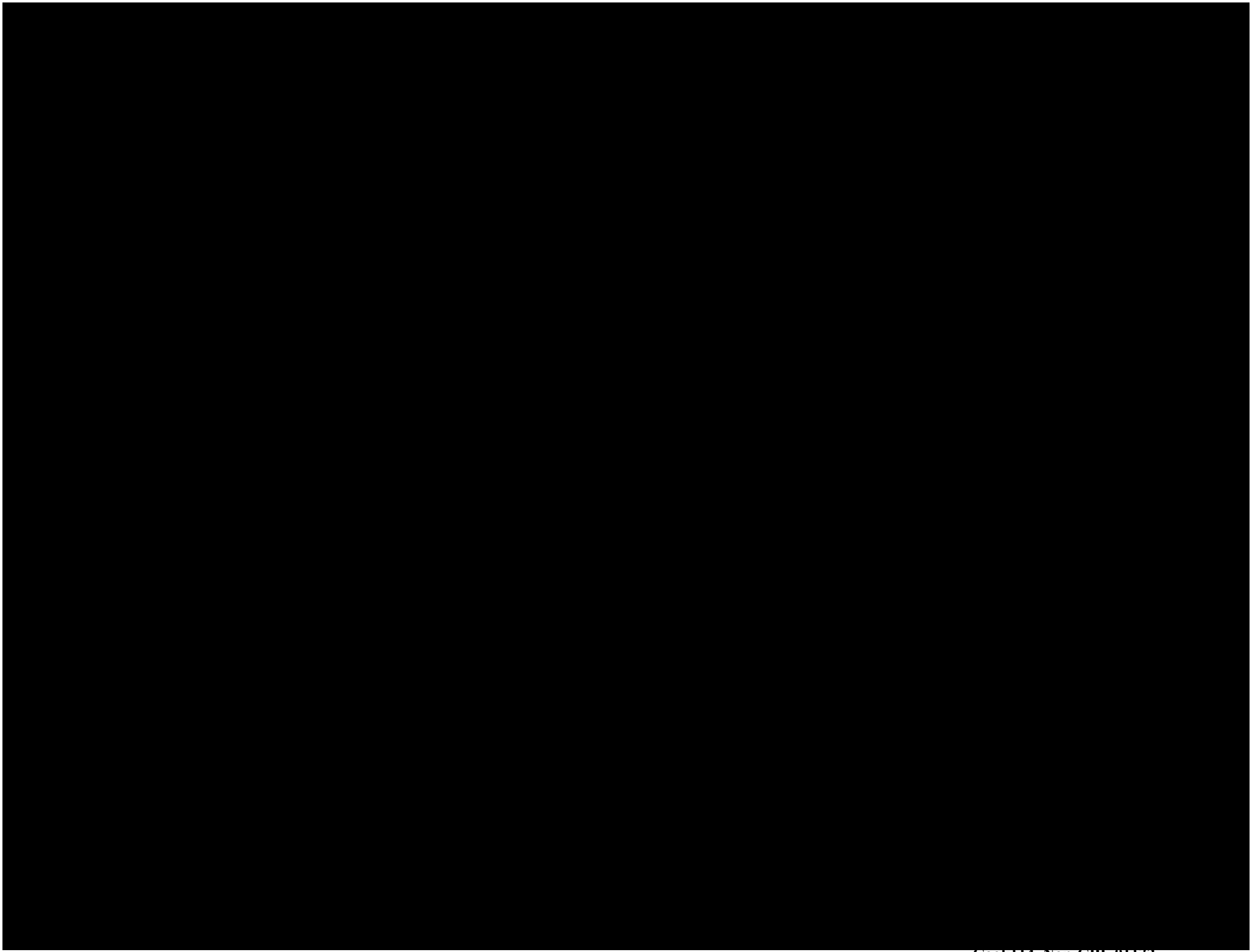

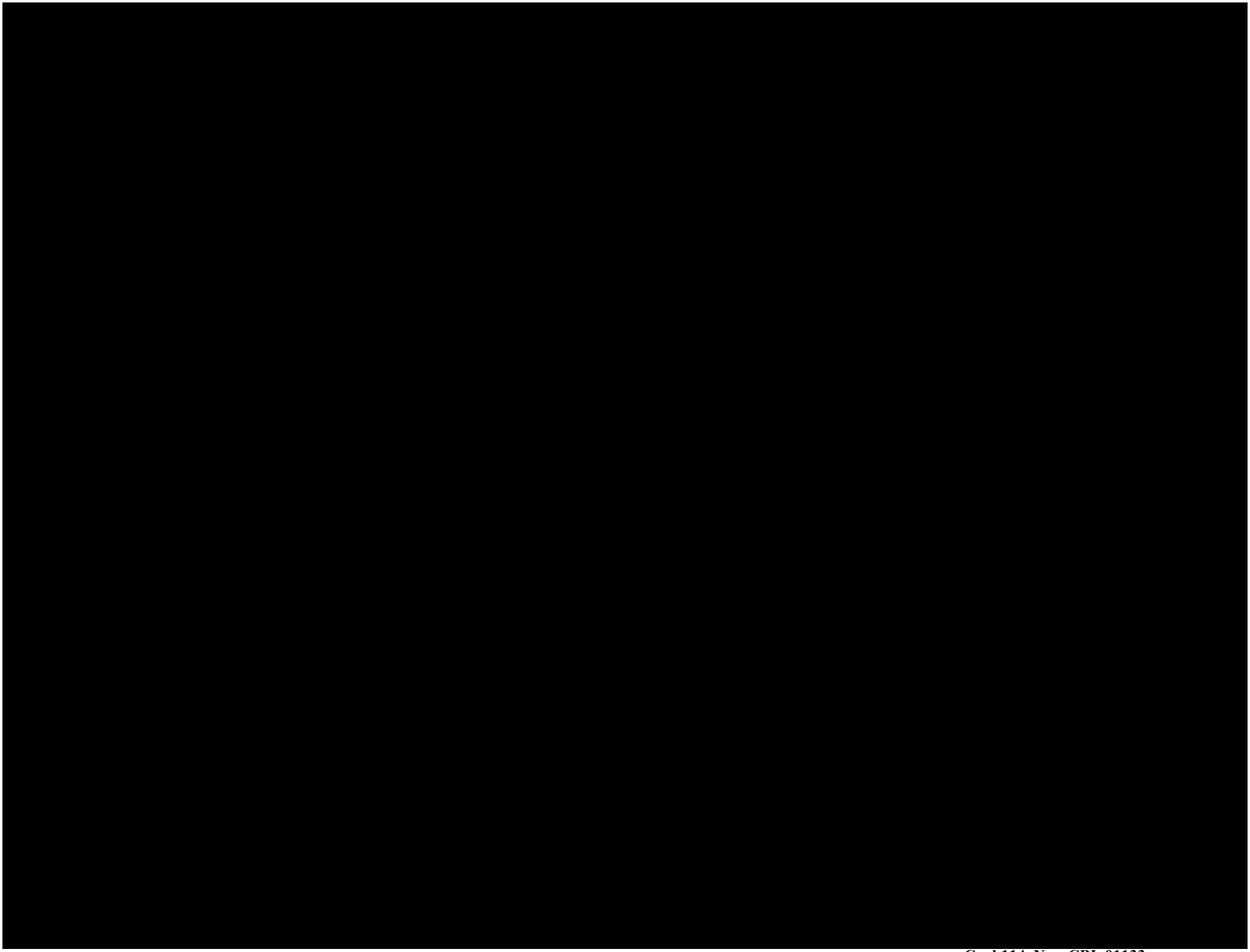

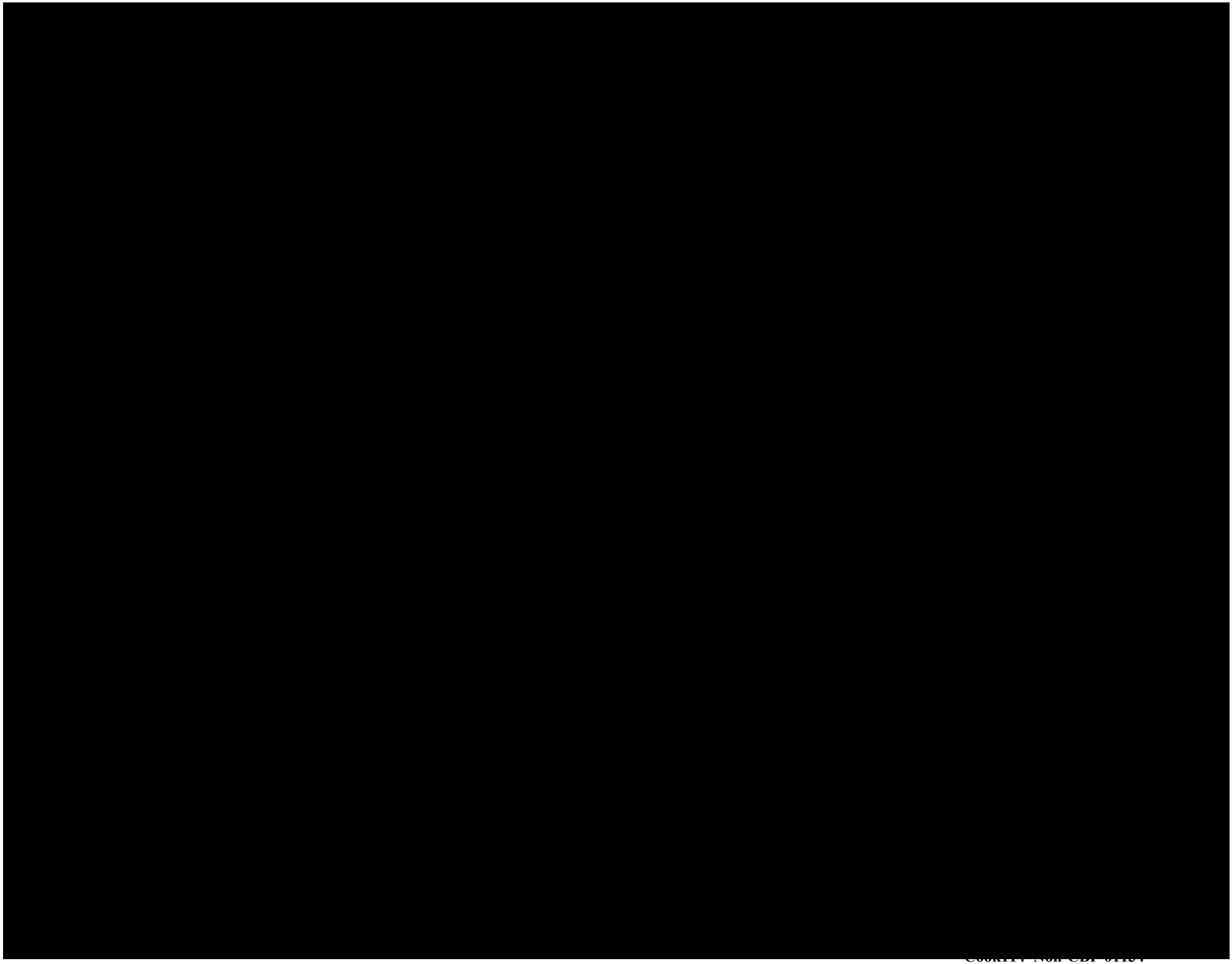

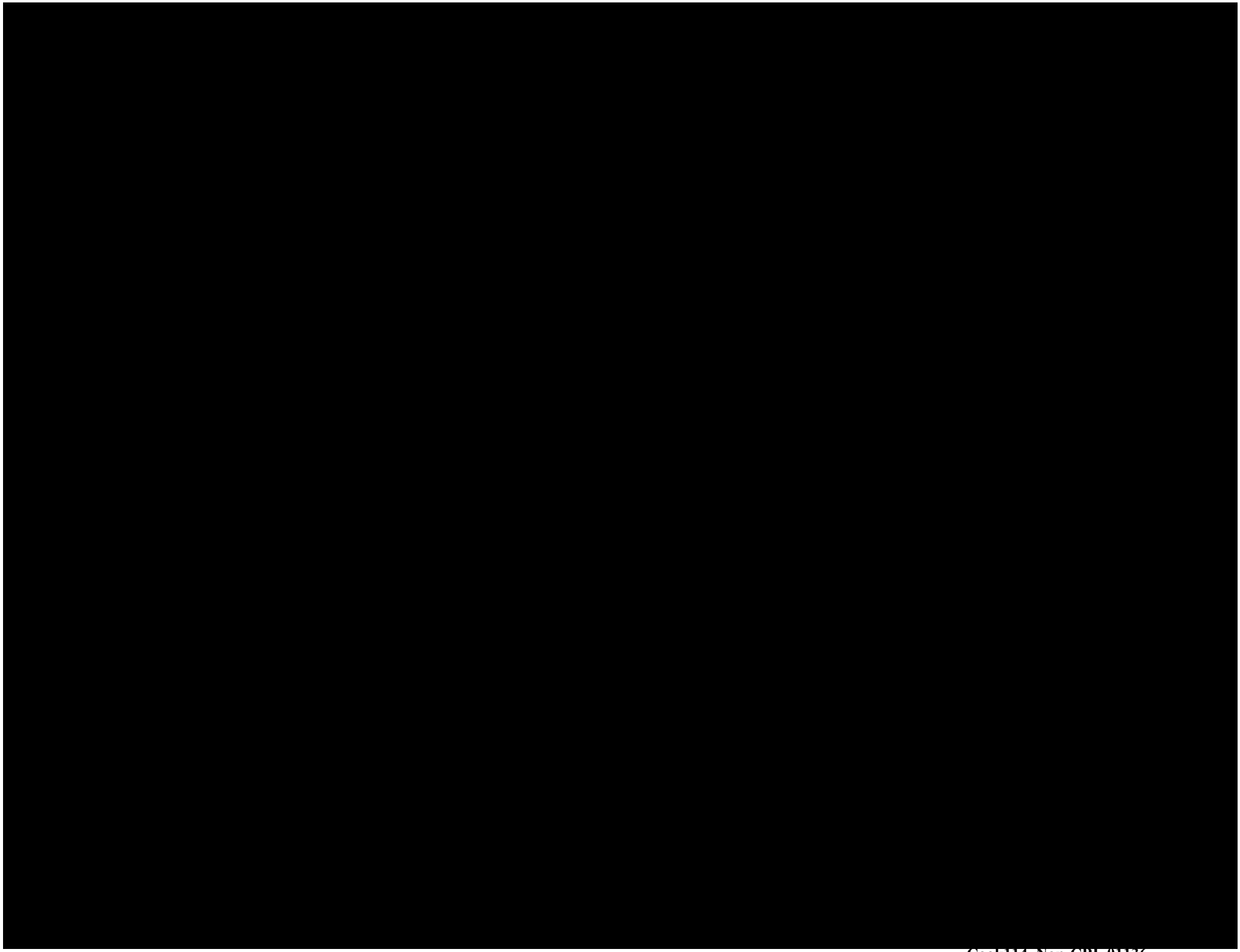

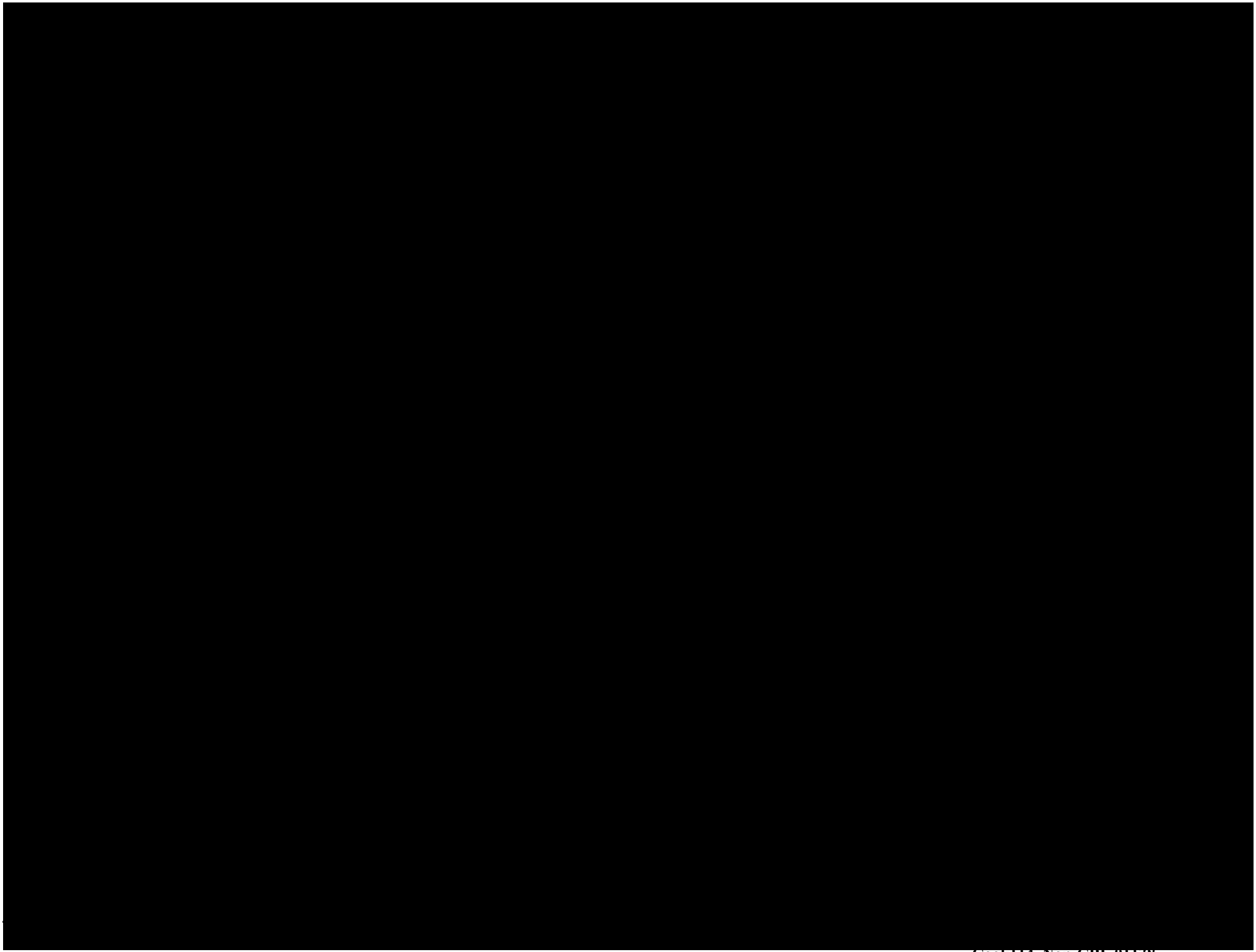

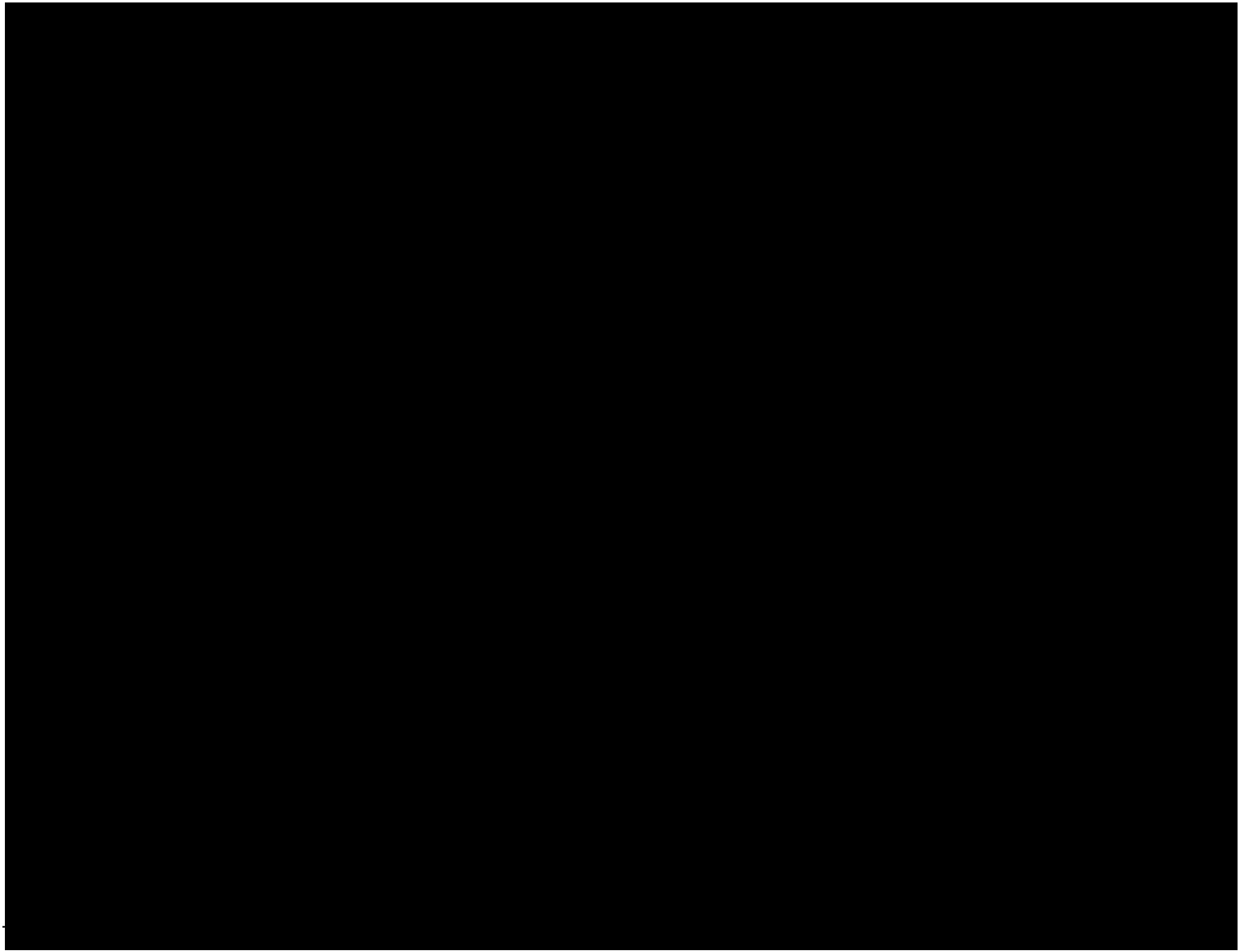

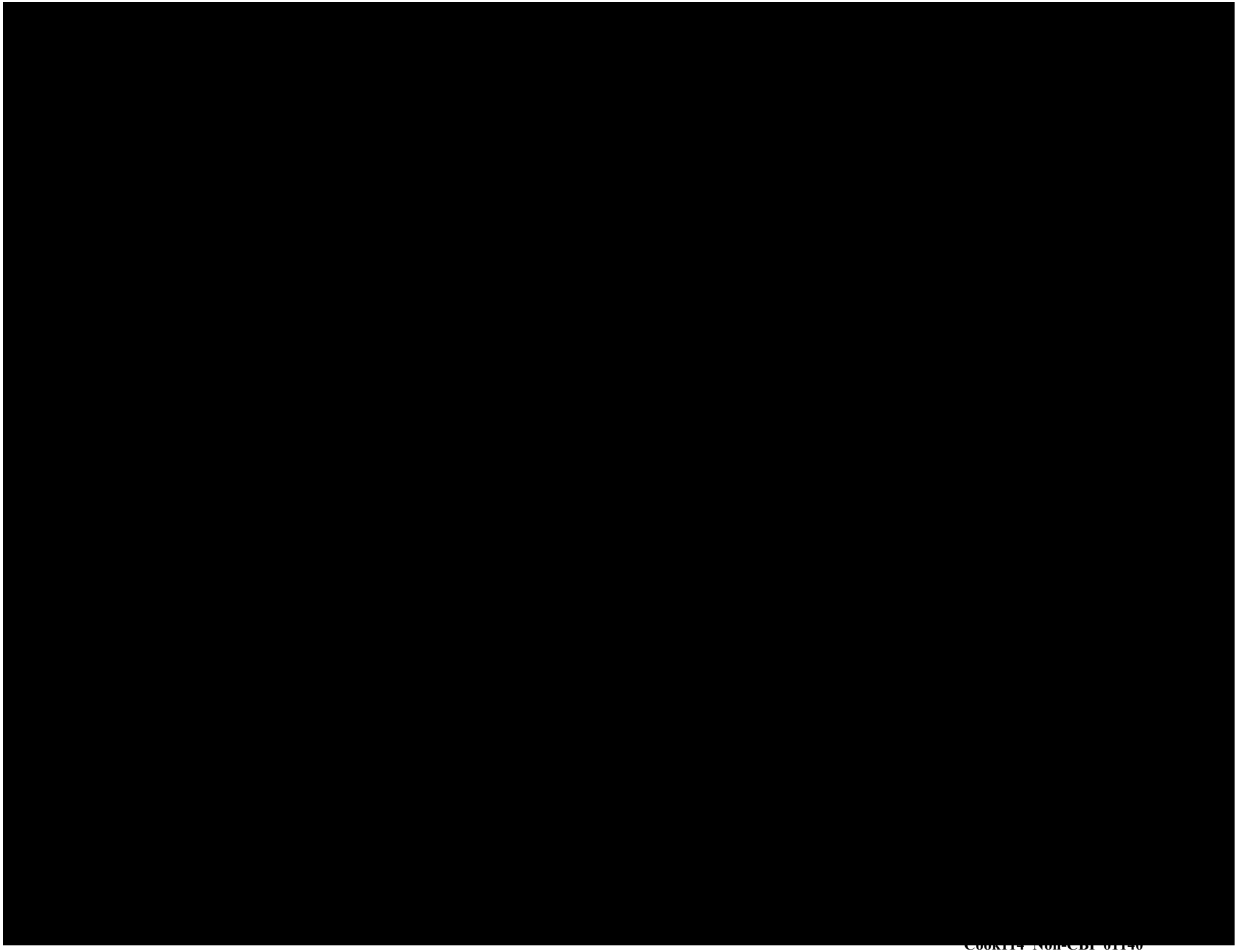

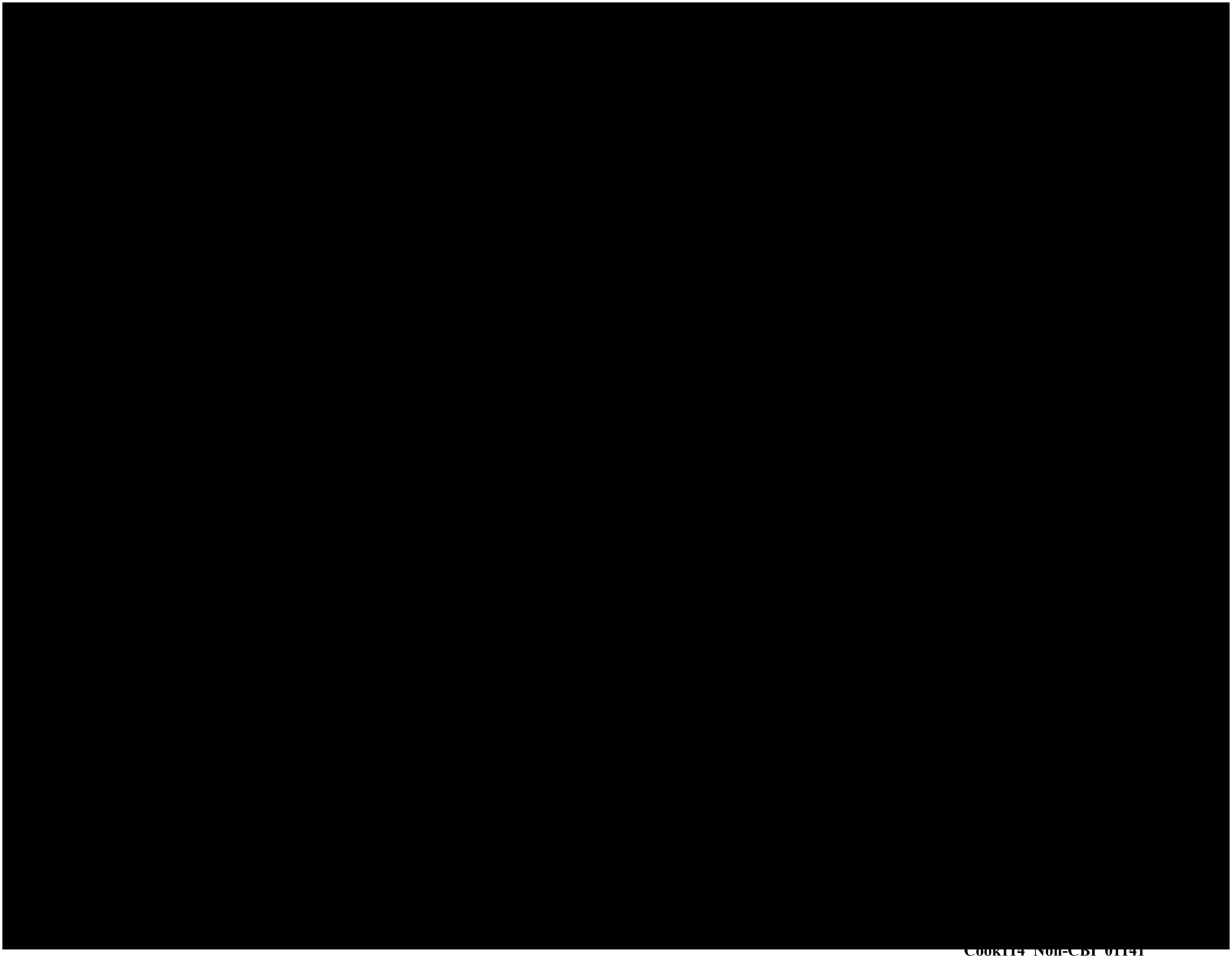

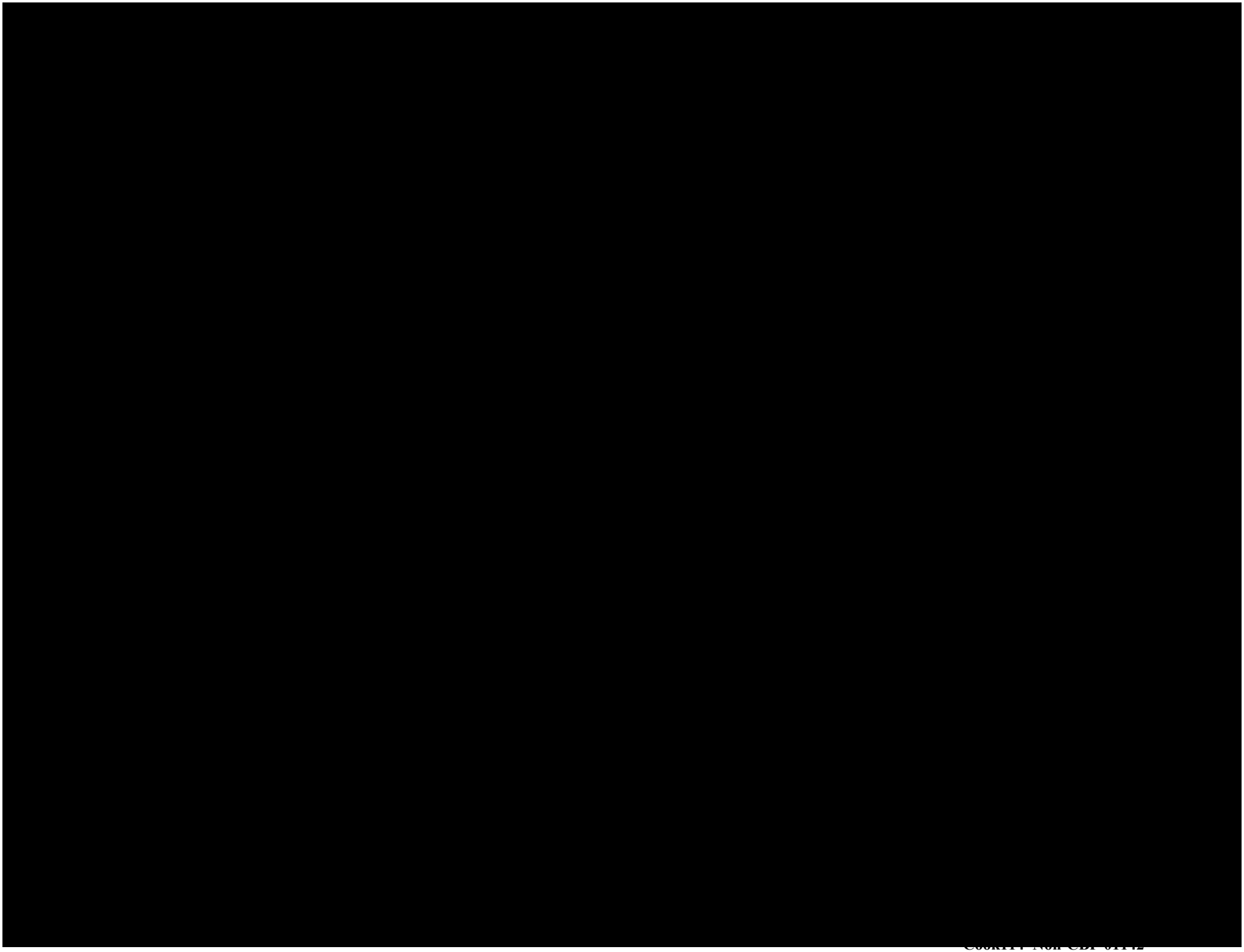

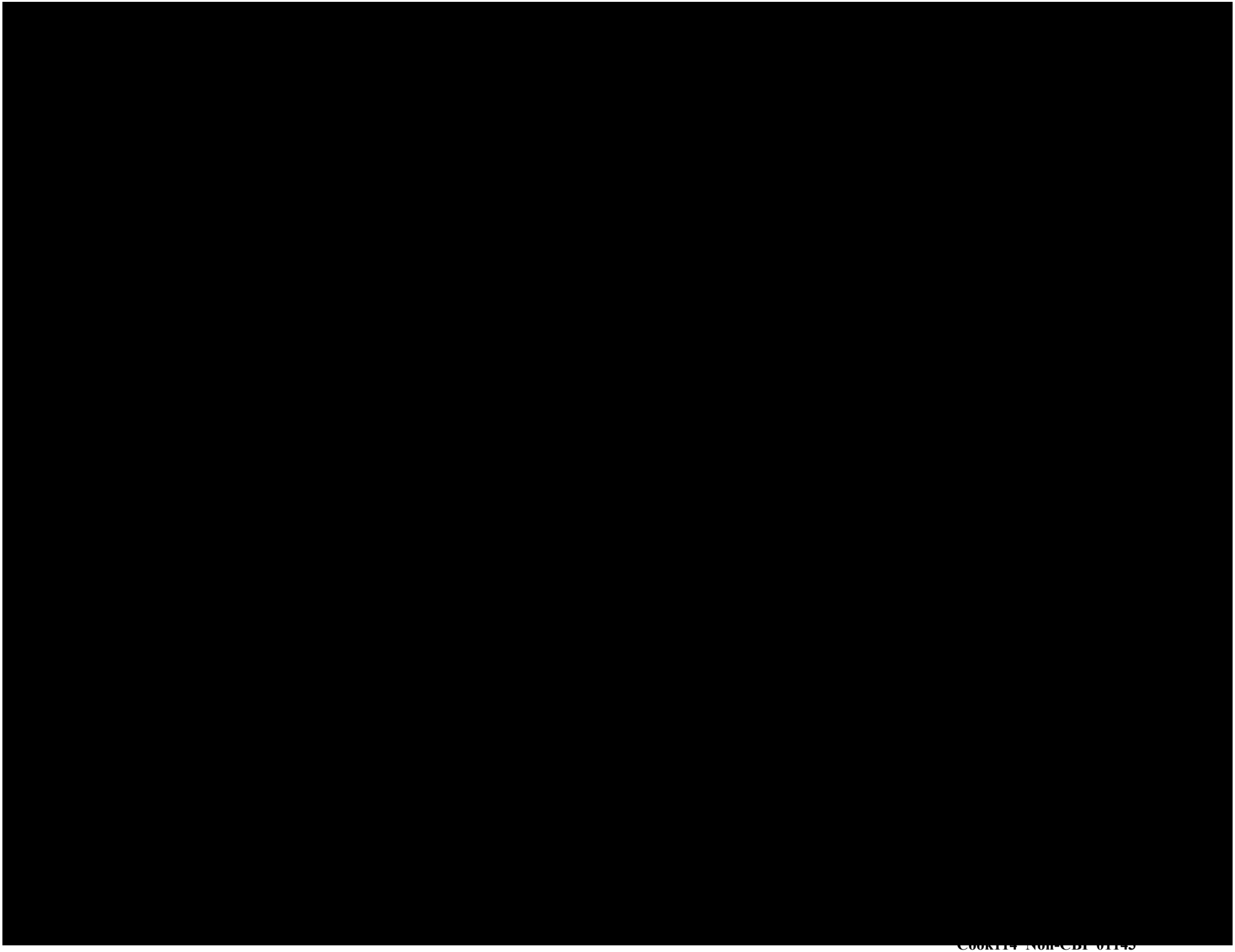

SCV Test #3

Sterilizers S9

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